Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

FY 2022

Medication-Assisted Treatment – Prescription Drug and Opioid Addiction

(Short Title: MAT-PDOA)

(Initial Announcement)

Notice of Funding Opportunity (NOFO) No. TI-22-013

Assistance Listing Number: (CFDA) No.: 93.243

Key Dates:

Application Deadline	Applications are due by April 29, 2022.	
Intergovernmental Review (E.O. 12372)	Applicants must comply with E.O. 12372 if their state(s) participate(s). Review process recommendations from the State Single Point of Contact (SPOC) are due no later than 60 days after application deadline.	
Public Health System Impact Statement (PHSIS)/Single State Agency Coordination	Applicants must send the PHSIS to appropriate state and local health agencies by the administrative deadline. Comments from the Single State Agency are due no later than 60 days after the application deadline.	

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EXECUTIVE SUMMARY

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), is accepting applications for fiscal year (FY) 2022 for the Medication-Assisted Treatment – Prescription Drug and Opioid Addiction. The purpose of this program is to provide resource to help expand/enhance access to Medications for Opioid Use Disorder (MOUD). It is expected that this program will help to 1) increase the number of individuals with Opioid Use Disorder (OUD) receiving MOUD; and 2) decrease illicit opioid use and prescription opioid misuse.

Funding Opportunity Title:	Medication-Assisted Treatment – Prescription Drug and Opioid Addiction (Short Title: MAT-PDOA)
Funding Opportunity Number:	TI-22-013
Due Date for Applications:	April 29, 2022
Estimated Total Available Funding:	Up to \$22,575,000
	(No less than \$11 million for MAT-PDOA grants will be provided to Indian tribes, tribal organizations, or consortia.)
Estimated Number of Awards:	Up to 30 awards
	(Up to 22 awards for tribal applicants)
Estimated Award Amount:	Up to \$750,000 per year per award
Cost Sharing/Match Required:	No
Anticipated Project Start Date:	9/30/2022
Anticipated Award Date	9/1/2022
Length of Project Period:	Up to 5 years
Eligible Applicants:	Eligible applicants are domestic public and private non- profit entities
	[See <u>Section III-1</u> for complete eligibility information.]
Authorizing Statute	MAT-PDOA grants are authorized under Section 509 of the Public Health Services Act, as amended; 42 U.S.C 290bb-2.

Be sure to check the SAMHSA website periodically for any updates on this program.

All applicants MUST register with NIH's eRA Commons in order to submit an application. This process takes up to six weeks. If you believe you are interested in applying for this opportunity, you MUST start the registration process immediately. Do not wait to start this process.

WARNING: BY THE DEADLINE FOR THIS NOFO YOU MUST HAVE SUCCESSFULLY COMPLETED THE FOLLOWING TO SUBMIT AN APPLICATION:

- The applicant organization MUST be registered in NIH's eRA Commons;
 AND
- The Project Director MUST have an active eRA Commons account (with the PI role) affiliated with the organization in eRA Commons.

No exceptions will be made.

Applicants also must register with the System for Award Management (SAM) and Grants.gov (see Appendix A of this NOFO for all registration requirements).

DO NOT WAIT UNTIL THE LAST MINUTE TO SUBMIT THE APPLICATION. If you wait until the last minute, there is a strong possibility that the application will not be received without errors by the deadline.

I. PROGRAM DESCRIPTION

1. PURPOSE

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), is accepting applications for fiscal year (FY) 2022 for the Medication-Assisted Treatment – Prescription Drug and Opioid Addiction. The purpose of this program is to provide resources to help expand/enhance access to Medications for Opioid Use Disorder (MOUD). It is expected that this program will help to 1) increase the number of individuals with Opioid Use Disorder (OUD) receiving MOUD; and 2) decrease illicit opioid use and prescription opioid misuse.

Providing FDA-approved medications for the treatment of OUD (methadone, buprenorphine/naloxone products/buprenorphine products including sublingual tablets/film, buccal film, and extended release, long-acting injectable buprenorphine formulations and injectable naltrexone) in an ongoing manner is a required activity of the program. MOUD is to be provided in combination with comprehensive psychosocial services, including counseling, behavioral therapies, recovery support services (RSS), and other clinically appropriate services. The exact combination of services for any given individual should be determined through a comprehensive assessment and tailored to each individual's needs and treatment goals that may include achieving and sustaining remission and recovery from OUD.

MAT-PDOA grants are authorized under Section 509 of the Public Health Services Act, as amended; 42 U.S.C 290bb-2.

2. KEY PERSONNEL

Key personnel are staff members who must be part of the project regardless of whether they receive a salary or compensation from the project. These staff members must make a substantial contribution to the execution of the project.

The key personnel for this program are the Project Director (person responsible for overseeing, monitoring, and managing the grant) at a minimum of at least a .50 FTE (50 percent level of effort) and the Program Evaluator (person responsible for evaluating the processes and outcomes of the grant) at a minimum of at least .25 FTE (25 percent level of effort). These positions require prior approval by SAMHSA after a review of staff credentials and job descriptions.

3. REQUIRED ACTIVITIES

Required activities are the activities that every grant recipient must implement. They must be reflected in the Project Narrative of your application. This is in response to Section V of this NOFO.

Project implementation is expected to begin by the <u>fourth month</u> from the date that grant funding is made available.

Applicants must indicate the total number of unduplicated individuals that will be served each year of the grant and over the total project period. You are expected to achieve the numbers that are proposed.

You must use SAMHSA's services grant funds primarily to support direct services. This includes the following activities:

- Provide MOUD with at least one of the FDA-approved medications (e.g., methadone, buprenorphine/naloxone products/buprenorphine products including sublingual tablets/film, buccal film, and extended release, long-acting injectable buprenorphine formulations and injectable naltrexone) in combination with comprehensive psychosocial services, counseling, behavioral therapies, RSS, and other clinically appropriate services.
- Conduct clinical assessment to establish the diagnosis and severity level of OUD based on DSM-5 diagnostic criteria and with information necessary to identify a recommended level of care and develop an individualized treatment and recovery plan.
- Check the state, county, or local Prescription Drug Monitoring Program (PDMP), where available, for each new patient admission in compliance with any relevant state rules or regulations.
- Conduct screening and assessment for co-occurring substance use and mental disorders and develop a plan to either deliver or coordinate any services determined to be necessary to address any identified co-occurring disorders.
- Develop and implement outreach and engagement strategies to increase access to MOUD and related services for diverse populations with OUD.
- Ensure all applicable practitioners working on the grant-funded project obtain a DATA waiver to prescribe buprenorphine to more than 30 patients.
- Build funding mechanisms and service delivery models with rural and resource-limited counties and municipalities, organizations such as health plans, integrated health systems, universities, hospitals, including emergency departments, clinics, community-based organizations, law enforcement, community recovery organizations, faith-based organizations, and/or other local coalitions in order to provide a robust suite of treatment and RSS that effectively identify, engage, and retain individuals in OUD treatment and facilitate long-term

recovery. This also includes Opioid Treatment Programs (OTPs) such that access to OUD treatment with methadone is available for patients of grant recipients that may not themselves be able to offer this medication. Consideration should be given for establishing a hub and spoke model, particularly in areas with limited access to MOUD.

- Use telehealth services, or other innovative interventions, to reach, engage, and retain patients in treatment.
- Provide or develop formal partnerships to provide RSS, including peer recovery support services designed to improve access to and retention in care with MOUD and facilitate long-term recovery.
- Provide harm reduction services on site, either singularly or in collaboration with a community-based harm reduction organization. Harm reduction services funded under this grant must adhere to federal, state, and local laws, regulations, and other requirements related to such programs or services.¹

4. ALLOWABLE ACTIVITIES:

Allowable activities are an allowable use of grant funds but are not required. Recipients may use grant funds to provide any allowable activity if it does not interfere or prevent the grant recipient from performing all required activities and serve the total number of unduplicated individuals each year of the grant. Allowable activities may include:

Purchase and/or implement mobile and/or non-mobile medication units that
provide appropriate privacy and adequate space to administer and dispense
medications for OUD treatment in accordance with federal regulations.² The
following services may be provided in mobile medication units, assuming
compliance with all applicable federal, state, and local law:

[I]t is unlawful for any person to sell or offer for sale drug paraphernalia; to use the mails or any other facility of interstate commerce to transport drug paraphernalia; or to import or export drug paraphernalia." The term "drug paraphernalia" is defined as "any equipment, product, or material of any kind which is primarily intended or designed for use in manufacturing, compounding, converting, concealing, producing, processing, preparing, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance, possession of which is unlawful under this subchapter." 21 U.S.C. §863(d).

¹21 U.S.C. §863(a) states:

² Letter to OTP Directors, SOTAs and State Directors from Kimberly Nelson, Acting Director of CSAT https://www.samhsa.gov/sites/default/files/2021-letter-mobile-component.pdf
Letter to State Substance Abuse Director on the adoption of mobile medication units from Miriam Delphin-Rittmon, Assistant Secretary for SAMHSA https://www.samhsa.gov/sites/default/files/2021-letter-state-authorities-mobile.pdf

- o Administering and dispensing medications for opioid use disorder treatment
- Collecting samples for drug testing or analysis
- Dispensing of take-home medications
- In units that provide appropriate privacy and adequate space, conduct intake/initial psychosocial and appropriate medical assessments (with a full physical examination to be completed or provided within 14-days of admission)
- Initiating methadone or buprenorphine after an appropriate medical assessment has been performed
- o In units that provide appropriate privacy and have adequate space, other services, such as counseling, may be provided directly or when permissible through use of telehealth services. Non-mobile medication units may also offer the above services where space allows for quality patient care and are consistent with state and local laws and regulations.
- Implement evidence-based contingency management interventions to treat stimulant use disorder and concurrent substance misuse to improve retention in care.
- Develop and implement tobacco cessation programs, activities, and/or strategies for people with OUD who are receiving MOUD.
- Outreach and screening to identify incarcerated individuals who are within four months from release and may benefit from MOUD services upon release from a jail or detention facility. Grant funds may be used to provide MOUD to incarcerated individuals within four months of release.
- Grant recipients may use up to \$25,000 for the purchase of Technical Assistance services for the project. If recipients opt not to use this for TA, the funds can be used for any other required/allowable activities of the grant. TA could be used to purchase training/TA to support client outreach, engagement, retention and/or follow-up, recipient staff retention (decrease in staff-turnover), use of evidence-based Interventions for the provision of care and services such as harm reduction strategies, improvement with client data collection, and continuous quality improvement.
- Education, screening, care coordination, risk reduction interventions, testing, and counseling for HIV/AIDS, hepatitis, and other infectious diseases for people with OUD who are receiving MOUD.
- Recovery housing: Recovery housing is one component of the SUD treatment and recovery continuum of care. While recovery residences vary widely in structure, all are centered on peer support and a connection to services that promote long-term recovery. Individuals in recovery should have a meaningful role in developing the service array used in their recovery plan. Recovery houses are safe, healthy, family-like substance-free living environments that support individuals in recovery from addiction. Substance-free does not prohibit prescribed medications taken as directed by a licensed practitioner, such as pharmacotherapies specifically approved by the Food and Drug Administration (FDA) for treatment of opioid use disorder as well as

other medications with FDA-approved indications for the treatment of co-occurring health conditions. Recipients must describe the mechanism(s) in place in their jurisdiction to assure that a recovery housing facility to receive these funds supports and provides clients access to evidence-based treatment, including all forms of MOUD, in a safe and appropriate setting. Recipients must also describe how recovery housing supported under this grant is in an appropriate and legitimate facility (e.g., state or other credentialing or certification or an established or recognized model).

 Develop and implement a low threshold approach that offers services and makes minimal requirements of patients, thus removing or reducing barriers to treatment and expanding access to care.

Infrastructure Development: (maximum 15 percent of total grant award for the budget period)

Although services grant funds must be used primarily for direct services, SAMHSA recognizes that infrastructure changes may be needed to implement the services or improve their effectiveness. You may use no more than 15 percent of the total grant award for the types of infrastructure development listed below, if necessary, to support the direct service expansion of the grant project. You must describe in Section B of your Project Narrative the use of grant funds for infrastructure activities which may include:

- Developing partnerships with other service providers and stakeholders serving the population of focus.
- Adopting and/or enhancing your computer system, management information system (MIS), electronic health records (EHRs), etc., to document and manage client needs, care process, integration with related support services, and outcomes.
- Training/workforce development to help project staff gain skills necessary to utilize new computer system/management information system/ EHRs, etc. funded through this service grant.
- Training/workforce development to help your staff or other providers in the community identify mental health or substance use disorder issues or provide effective services consistent with the purpose of the grant program.
- Policy development to support needed service system improvements (e.g., ratesetting activities, establishment of standards of care, adherence to the <u>Behavioral</u> <u>Health Guide for the National Standards for Culturally and Linguistically</u>

<u>Appropriate Services (CLAS) in Health and Health Care</u>, development/revision of credentialing, licensure, or accreditation requirements).³

5. USING EVIDENCE-BASED PRACTICES

SAMHSA's services grants are intended to fund services or practices that have a demonstrated evidence base and that are appropriate for the population(s) of focus. An evidence-based practice (EBP) refers to approaches to prevention, harm reduction, treatment, or recovery that are validated by some form of documented research evidence. Both researchers and practitioners recognize that EBPs are essential to improving the effectiveness of treatment and prevention services. While SAMHSA realizes that EBPs have not been developed for all populations and/or service settings, application reviewers will closely examine proposed interventions for evidence base and appropriateness for the population of focus. If an EBP(s) exists for the population(s) of focus and types of problems or disorders being addressed, the expectation is that EBP(s) will be utilized. If one does not exist but there are evidence-informed and/or culturally promising practices that are appropriate or can be adapted, these interventions may be implemented in the delivery of services.

In your Project Narrative, in response to Section C of Section V of this NOFO, you will need to identify the evidence-based practice(s) and/or interventions that are evidence-informed and/or culturally promising that are appropriate or can be adapted to meet the needs of your specific population(s) of focus. You must discuss the population(s) for which the practice(s) has (have) been shown to be effective and document that it is (they are) appropriate for your population(s) of focus. You must also address how these interventions will improve outcomes and address how you will monitor and ensure fidelity of EBPs and other appropriate interventions.

Applicants are encouraged to visit the SAMHSA Evidence-Based Practice Resource Center (www.samhsa.gov/ebp-resource-center) and SAMHSA's National Network to Eliminate Disparities in behavioral health (NNED) (https://nned.net/) to identify evidence-informed and culturally appropriate mental illness and substance use prevention and treatment practices that can be implemented in your project.

³ For purposes of this NOFO efforts do not include activities designed to influence the enactment of legislation, appropriations, regulations, administrative actions, or Executive Orders ("legislation and other orders") proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, and awardees may not use federal funds for such activities. This restriction extends to both grassroots lobbying efforts and direct lobbying. However, for state, local, and other governmental recipients, certain activities falling within the normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government are

not considered impermissible lobbying activities and may be supported by federal funds.

6. DATA COLLECTION/PERFORMANCE MEASUREMENT AND PROJECT PERFORMANCE ASSESSMENT

Data Collection/Performance Measurement

All SAMHSA recipients are required to collect and report certain data so that SAMHSA can meet its obligations under the Government Performance and Results (GPRA) Modernization Act of 2010. You must document your plan for data collection and reporting in your Project Narrative in response to Section E: Data Collection and Performance Measurement in Section V of this NOFO.

Recipients are required to collect and report data on the following performance measures: abstinence from use, types of MOUD received, housing status, employment status, criminal justice system involvement, access to services, retention in services (including medication therapies), social connectedness, and units of analysis, including measures of disparities in access, service use, and outcomes across subpopulations.

This information will be gathered using a uniform data collection tool provided by SAMHSA. Recipients are required to submit data via SAMHSA's Performance Accountability and Reporting System (SPARS); and access will be provided upon award. An example of the required data collection tool (i.e., National Outcome Measures (NOMs) or NOMS client level services tool) can be found here https://www.samhsa.gov/grants/gpra-measurement-tools/csat-gpra/csat-gpra-discretionary-services

Data will be collected by interview or by telephone using this tool at three data collection points: intake to services, six months post intake, and at discharge. Recipients will be expected to do a GPRA interview of all clients in their specified unduplicated target number and are also expected to achieve a six-month follow-up rate of 80 percent. All data must be submitted through the specified online data submission tool within seven days of data collection or as specified after award. Recipients will be provided extensive training on the system and its requirements post award.

The collection of these data enables SAMHSA to report on key outcome measures relating to the grant program. In addition to these outcomes, data collected by recipients will be used to demonstrate how SAMHSA's grant programs are reducing disparities in behavioral health access, service use, and outcomes nationwide. As a result, SAMHSA may add additional reporting measures throughout the reporting period to meet these needs.

Performance data will be reported to the public as part of SAMHSA's Congressional Budget Justification.

Project Performance Assessment

Recipients must periodically review the performance data they report to SAMHSA (as required above), assess their progress, and use this information to improve the management of their grant project. Recipients are also required to report on their progress addressing the goals and objectives identified in your Project Narrative.

The project performance assessment should be designed to help you determine whether you are achieving the goals, objectives, and outcomes you intend to achieve and whether adjustments need to be made to your project. Performance assessments should be used to determine whether your project is having/will have the intended impact on behavioral health disparities.

Note: See Appendix E and Appendix F of this NOFO for more information on responding to this section.

7. OTHER EXPECTATIONS

SAMHSA Values That Promote Positive Behavioral Health

SAMHSA expects recipients to use grant funds to implement high quality programs, practices, and policies that are <u>recovery-oriented</u>, <u>trauma-informed</u>, and <u>equity-based</u> as a means of improving behavioral health.⁴

Recovery is "a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential." Recovery oriented systems of care promote partnering with people in recovery from mental and substance use disorders and their family members to guide the behavioral health system and promote individual, program, and system-level approaches that foster: *Health*—managing one's illnesses or symptoms and making informed healthy choices that support physical and emotional wellbeing; *Home*—a stable and safe place to live; *Purpose*—meaningful daily activities such as a job or school; and *Community*—supportive relationships with families, friends and peers.

<u>Trauma-informed care</u> recognizes and intentionally responds to the lasting adverse effects of experiencing traumatic events (e.g., domestic violence, war, sexual abuse, generational trauma, etc.). Principles of recovery and trauma-informed care include: *Hope*–emphasizing that change, growth and healing are real and possible; *Person-Driven*-optimizing autonomy and independence; *Many Pathways*—adopting individualized approaches; *Respect*—treating all with dignity and respect and protecting

⁴ "<u>Behavioral health</u>" means the promotion of mental health, resilience and wellbeing; the treatment of mental and substance use disorders; and the support of those who experience and/or are in recovery from these conditions, along with their families and communities.

rights; Safety-assuring all are physically and psychologically safe; Trustworthiness and Transparency—conducting transparent operations and decisions to build trust; Collaboration and Mutuality- leveling power differences to facilitate healing relationships; and Cultural, Historical, & Gender Issues—actively moving beyond stereotypes/biases while offering culture and gender-responsive services including traditional cultural practices and addressing historical trauma. A key element of recovery and trauma-informed care is the full inclusion of people with lived experience and their family members in the design, delivery, and evaluation of behavioral health services and policies.

Behavioral health equity is the right to access high quality and affordable health care services and supports for all populations regardless of the individual's race, age, ethnicity, gender, disability, socioeconomic status, sexual orientation, or geographical location. Advancing behavioral health equity involves ensuring that everyone has a fair and just opportunity to be as healthy as possible. In conjunction with quality services, this involves addressing social determinants of health, such as employment and housing stability, insurance status, proximity to services, and culturally responsive care – all of which have an impact on behavioral health outcomes.

Behavioral Health Disparities

If your application is funded, you will be expected to develop a behavioral health disparity impact statement no later than 60 days after your award. (See <u>Appendix H</u> – Addressing Behavioral Health Disparities).

The behavioral health disparity impact statement is in alignment with the expectations related to Executive Order 13985 "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government."

Tribal Behavioral Health Agenda

SAMHSA, working with tribes, the Indian Health Service, and National Indian Health Board developed the first collaborative National Tribal Behavioral Health Agenda (TBHA). Tribal applicants are encouraged to briefly cite the applicable TBHA foundational element(s), priority(ies), and strategies that are addressed by their grant application. The TBHA can be accessed at http://nihb.org/docs/12052016/FINAL%20TBHA%2012-4-16.pdf.

Tobacco and Nicotine Free Policy

SAMHSA strongly encourages all recipients to adopt a tobacco/nicotine inhalation (vaping) product-free facility/grounds policy and to promote abstinence from all tobacco products (except in regard to accepted tribal traditions and practices).

Reimbursements for the Provision of Services

Recipients must utilize third party reimbursements and other revenue realized from the provision of services to the extent possible and use SAMHSA grant funds only for services to individuals who are not covered by public or commercial health insurance programs, individuals for whom coverage has been formally determined to be unaffordable, or for services that are not sufficiently covered by an individual's health insurance plan. Recipients are also expected to facilitate the health insurance application and enrollment process for eligible uninsured clients. Recipients should also consider other systems from which a potential service recipient may be eligible for services (for example, the Veterans Health Administration or senior services), if appropriate for and desired by that individual to meet his/her needs. In addition, recipients are required to implement policies and procedures that ensure other sources of funding are utilized first when available for that individual.

Behavioral Health for Military Service Members and Veterans

SAMHSA encourages all recipients to address the behavioral health needs of activeduty military service members, returning veterans, and military families in designing and developing their programs and to consider prioritizing this population for services, where appropriate.

8. GRANTEE MEETINGS

Recipient meetings will be held virtually, and recipients are expected to fully participate in these meetings. If SAMHSA elects to hold an in-person meeting, budget revisions will be permitted.

II. FEDERAL AWARD INFORMATION

1. GENERAL INFORMATION

Funding Mechanism: Grant

Estimated Total Available Funding: Up to \$22,575,000

Estimated Number of Awards: 30 Awards (Up to 22 awards for tribal

applicants)

Estimated Award Amount: Up to \$750,000 per year per award

Length of Project Period: Up to 5 years

Anticipated Start Date: 9/30/2022

Proposed budgets cannot exceed \$750,000.00 in total costs (direct and indirect) in any year of the proposed project. Annual continuation awards will depend on the availability of funds, recipient progress in meeting project goals and objectives, timely submission of required data and reports, and compliance with all terms and conditions of award.

Funding estimates for this announcement are based on an annualized Continuing Resolution and do not reflect the final FY 2022 appropriation. Applicants should be aware that funding amounts are subject to the availability of funds.

III. ELIGIBILITY INFORMATION

1. ELIGIBLE APPLICANTS

Eligible applicants are:

• Domestic public and private non-profit entities including federally recognized American Indian/Alaska Native (AI/AN) tribes/tribal organizations.

All non-profit entities must submit documentation of their non-profit status in **Attachment 8** of your application.

This NOFO includes a \$11 million set-aside for Indian tribes, tribal organizations, or consortia, per congressional mandate.

Tribal organization means the recognized body of any Al/AN tribe; any legally established organization of Al/ANs which is controlled, sanctioned, or chartered by such governing body, or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Al/ANs in all phases of its activities. Consortia of tribes or tribal organizations are eligible to apply, but each participating entity must indicate its approval. A single tribe in the consortium must be the legal applicant, the recipient of the award, and the entity legally responsible for satisfying the grant requirements.

Urban Indian Organization (UIO) (as identified by the Indian Health Service Office of Urban Indian Health Programs through active Title V grants/contracts) means a non-profit corporate body situated in an urban center governed by an urban Indian-controlled board of directors, and providing for the maximum participation of all interested Individuals and groups, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in 503(a) of 25

U.S.C. § 1603. UIOs are not tribes or tribal governments and do not have the same consultation rights or trust relationship with the federal government.

It is recommended that you review information on eligibility in Appendix C of this NOFO.

2. COST SHARING AND MATCHING REQUIREMENTS

Cost sharing/match is not required in this program.

3. OTHER REQUIREMENTS

- MAT-PDOA recipients who received funding in FY20 under TI-18-009 and in FY21 under TI-21-006 are not eligible to apply for this funding opportunity.
- The Project Narrative must not exceed 10 pages. If the Project Narrative is over 10 pages, the application will not be considered for review.

• Evidence of Experience and Credentials

SAMHSA believes that only existing, experienced, and appropriately credentialed organizations with demonstrated infrastructure and expertise will be able to provide the required services quickly and effectively. All Required Activities must be provided by applicants directly, by subrecipients, or through referrals to applicant partner agencies. Applicants must submit evidence under Attachment 1 of their application meeting three additional requirements related to the provision of services.

The three requirements are:

- A provider organization for direct client substance use disorder treatment services appropriate to the grant must be involved in the proposed project. The provider may be the applicant, or another organization committed to the project. More than one provider organization may be involved.
- Each mental health/substance use disorder treatment provider organization must have at least two years of experience (as of the due date of the application) providing relevant services (official documents must establish that the organization has provided relevant services for the <u>last two years</u>).
- Each mental health/substance use disorder treatment provider organization must comply with all applicable local (city, county) and

state licensing, accreditation, and certification requirements, as of the due date of the application.

The above requirements apply to all service provider organizations. A license from an individual clinician will not be accepted in lieu of a provider organization's license. Eligible tribes and tribal organization mental health/substance use disorder treatment providers must comply with all applicable tribal licensing, accreditation, and certification requirements, as of the due date of the application. In Attachment 1, you must include a letter certifying that the service provider organizations meet these requirements.

Following application review, if your application's score is within the fundable range, the GPO may contact you to request that additional documentation be sent by email or uploaded through eRA Commons, or to verify that the documentation you submitted is complete. If the GPO does not receive this documentation within the time specified, your application will not be considered for an award.

IV. APPLICATION AND SUBMISSION INFORMATION

1. ADDRESS TO REQUEST APPLICATION PACKAGE

The application forms package specific to this funding opportunity can be accessed through <u>Grants.gov Workspace</u> or <u>eRA ASSIST</u>. Due to difficulties with internet access, SAMHSA understands that applicants may have a need to request paper copies of materials, including forms and required documents. See <u>Appendix A</u> for more information obtaining an application package.

2. CONTENT AND FORM OF APPLICATION SUBMISSION

REQUIRED APPLICATION COMPONENTS:

The standard and supporting documents that must be submitted with the application are outlined below and in <u>Appendix A - 2.2</u> Required Application Components of this NOFO.

All files uploaded as part of the application must be in Adobe PDF file format. See Appendix B of this NOFO for formatting and validation requirements.

SAMHSA will not accept paper applications except under very special circumstances. If you need special consideration, SAMHSA must approve the waiver

of this requirement in advance. See <u>Appendix A</u> - 3.2 Waiver of Electronic Submission of this NOFO.

- **SF-424** Fill out all Sections of the SF-424.
 - In Line #4 (i.e., Applicant Identifier), input the Commons Username of the PD/PI.
 - o In **Line #17** input the following information: (Proposed Project Date: a. Start Date: 9/30/2022; b. End Date: 9/29/2027).
- **SF-424A BUDGET INFORMATION FORM –** Fill out all Sections of the SF-424A using instructions below. **The totals in Sections A, B, and D must match.**
 - Section A Budget Summary: If cost sharing/match is not required, use the first row only (Line 1) to report the total federal funds (e) and non-federal funds (f) requested for the <u>first year</u> of your project only. If cost sharing/match is required, use the second row (Line 2) to report the total non-federal funds (f) for the <u>first year</u> of your project only.
 - Section B Budget Categories: If cost sharing/match is not required, use the first column only (Column 1) to report the budget category breakouts (Lines 6a through 6h) and indirect charges (Line 6j) for the total funding requested for the <u>first year</u> of your project only. If cost sharing/match is required, you must use the second column (Column 2) to report the budget category breakouts for the <u>first year</u> of your project only.
 - Section C –If cost sharing/match is not required leave this section blank. If cost sharing/match is required use the second row (line 9) to report nonfederal match for the <u>first year</u> only.
 - Section D Forecasted Cash Needs: Input the total funds requested, broken down by quarter, only for Year 1 of the project period. Use the first row for federal funds and the second row (Line 14) for non-federal funds.
 - Section E Budget Estimates of Federal Funds Needed for the Balance of the Project: Enter the total funds requested for the out years (e.g., Year 2, Year 3, Year 4, and Year 5). For example, if you are requesting funds for four years in total, enter the requested budget amount for each budget period in columns b, c, and d (i.e., 4 out years). (b) First column is the budget for the second budget period; (c) Second column is the budget for the third budget period; (d) Third column is the budget for the fourth budget period. Use Line 16 for federal funds and Line 17 for non-federal funds and Line 17 for non-federal funds.

See <u>Appendix B</u> of this NOFO to review common errors in completing the SF-424 and the SF-424A. These errors will prevent your application from being successfully submitted.

A link to a sample budget form and justification is provided in <u>Appendix L</u> of this NOFO. It is highly recommended that you use this sample budget format. This will expedite review of your application.

PROJECT NARRATIVE – (Maximum 10 pages total)

The Project Narrative describes your project. It consists of Sections A through E. (Remember that if your Project Narrative starts on page 5 and ends on page 15, it is 11 pages long, not 10 pages.) More detailed instructions for completing each section of the Project Narrative are provided in <u>Section V.2</u> – Application Review Information.

BUDGET JUSTIFICATION AND NARRATIVE

The budget justification and narrative must be submitted as a file entitled "BNF" (Budget Narrative Form) when you submit your application into Grants.gov. (See Appendix A – 2.2 Required Application Components.)

ATTACHMENTS 1 THROUGH 9

Attachment 1: Evidence of Experience and Credentials

- 1. Identification of at least one experienced, licensed mental health/substance use treatment provider organization.
- 2. A list of all direct service provider organizations that have agreed to participate in the proposed project, including the applicant agency, if it is a service provider organization.
- Letters of Commitment from these direct service provider organizations; (Do not include any letters of support. Reviewers will not consider them if you do.)
- 4. A letter certifying that all listed providers have met the two-year experience requirement, are appropriately licensed, accredited, and certified, and that if the application is within the funding range for an award, the applicant will send the GPO the required documentation within the specified time.
- Attachment 2: Data Collection Instruments/Interview Protocols If you are using standardized data collection instruments/interview protocols, you do <u>not</u> need to include these in your application. Instead, provide a web link to the appropriate instrument/protocol. If the data collection instrument(s) or interview protocol(s) is/are not standardized, you must include a copy in Attachment 2.

- Attachment 3: Sample Consent Forms
 - Forms to be submitted include, as appropriate, sample consent forms that provide for: (1) informed consent for participation in service intervention; (2) informed consent for participation in the data collection component of the project; and (3) informed consent for the exchange (releasing or requesting) of confidential information.
- Attachment 4: Project Timeline
 This attachment is scored by reviewers. Maximum of 2 pages. See instructions in Section V, B.3 of this NOFO.
- Attachment 5: Biographical Sketches and Position Descriptions
 See Appendix G of this NOFO for information on completing biographical sketches and job descriptions. Position descriptions should be no longer than one page each and biographical sketches should be two pages or less.
- Attachment 6: Letter to the Single State Agency (SSA)
 See Appendix J of this NOFO for Intergovernmental Review (E.O. 12372)
 Requirements, if applicable.
- Attachment 7: Confidentiality and SAMHSA Participant Protection/ Human Subjects Guidelines
 This attachment is in response to <u>Appendix D</u> of this NOFO and is a required attachment.
- Attachment 8: Documentation of Non-profit Status
 All non-profit entities must submit documentation of their non-profit status. Any of the following is acceptable documentation:
 - Proof of nonprofit status must be submitted by private nonprofit organizations with the application. Any of the following is acceptable evidence of nonprofit status: a reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of taxexempt organizations described in section 501(c)(3) of the IRS Code;
 - A copy of a currently valid Internal Revenue Service tax exemption certificate.
 - A statement from a State taxing body, State Attorney General, or other appropriate state official certifying the applicant organization has a non-profit status;
 - A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status; or

- Any of the above proof for a state or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.
- Attachment 9: Form SMA 170 Assurance of Compliance with SAMHSA
 Charitable Choice Statutes and Regulations You are required to complete
 Form SMA 170 if your project is offering substance use prevention or
 treatment services. This form is posted on SAMHSA's website at
 http://www.samhsa.gov/grants/applying/forms-resources.

3. UNIQUE ENTITY IDENTIFIER AND SYSTEM FOR AWARD MANAGEMENT

See Appendix A for information about the four registration processes that must be completed including obtaining a Unique Entity Identifier and registering with the System for Award Management (SAM). You must continue to maintain an active SAM registration with current information during the period of time your organization has an active federal award or an application under consideration by an agency (unless you are an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), has an exception approved by the agency under 2 CFR § 25.110(d)).

4. APPLICATION SUBMISSION REQUIREMENTS

Applications are due by **11:59 PM** (Eastern Time) on **April 29, 2022**. If an organization is submitting more than one application; the project title should be different for each application.

If you have been granted permission to submit a paper copy, the application must be received by the above date and time. See Appendix A of this NOFO for information on how to submit the application.

All applicants MUST register with NIH's eRA Commons in order to submit an application. This process takes up to six weeks. If you believe you are interested in applying for this opportunity, you MUST start the registration process immediately. Do not wait to start this process.

WARNING: BY THE DEADLINE FOR THIS NOFO YOU MUST HAVE SUCCESSFULLY COMPLETED THE FOLLOWING TO SUBMIT AN APPLICATION:

- The applicant organization MUST be registered in NIH's eRA Commons;
 AND
- The Project Director MUST have an active eRA Commons account (with the PI role) affiliated with the organization in eRA Commons.

No exceptions will be made.

Applicants must also register with SAM and Grants.gov (see Appendix A for all registration requirements).

DO NOT WAIT UNTIL THE LAST MINUTE TO SUBMIT THE APPLICATION. If you wait until the last minute, there is a strong possibility that the application will not be received without errors by the deadline.

5. FUNDING LIMITATIONS/RESTRICTIONS

The funding restrictions for this project are below. Be sure to identify these expenses in your proposed budget.

- No more than 15 percent of the total grant award for the budget period may be used for developing the infrastructure necessary for expansion of services.
- No more than 20 percent of the total grant award for the budget period may be used for data collection, performance measurement, and performance assessment, including incentives for participating in the required data collection follow-up.
- Up to \$25,000 of the total grant award for the budget period can be used for the purchase of Technical Assistance (TA). If recipients opt not to use this amount for TA, the funds can be used for any other required/allowable activities of the grant.

 Grant funds may not be used solely for withdrawal management services, except when medically managed withdrawal is used as part of a process of induction onto Extended-release Naltrexone (XR-NXT).

SAMHSA recipients must also comply with SAMHSA's standard funding restrictions, which are included in Appendix I – Standard Funding Restrictions.

6. INTERGOVERNMENTAL REVIEW (E.O. 12372) REQUIREMENTS

All SAMHSA grant programs are covered under Executive Order (EO) 12372, as implemented through Department of Health and Human Services (HHS) regulation at 45 CFR Part 100. Under this Order, states may design their own processes for reviewing and commenting on proposed federal assistance under covered programs. See Appendix J for additional information on these requirements as well as requirements for the Public Health System Impact Statement (PHSIS).

7. OTHER SUBMISSION REQUIREMENTS

See Appendix A for specific information about submitting your application.

V. APPLICATION REVIEW INFORMATION

1. EVALUATION CRITERIA

The Project Narrative describes what you intend to do with your project and includes the Evaluation Criteria in Sections A-E below. Your application will be reviewed and scored according to your response to the requirements in Sections A-E.

In developing the Project Narrative section of your application, use these instructions, which have been tailored to this program.

- The Project Narrative (Sections A-E) together may be no longer than 10 pages.
- You must use the five sections/headings listed below in developing your Project Narrative. You <u>must</u> indicate the Section letter and number in your response, i.e., type "A-1", "A-2", etc., before your response to each question. You do not need to type the full criterion in each section. You only need to include the letter and number of the criterion. You may not combine two or more questions or refer to another section of the Project Narrative in your response, such as indicating that the response for B.2 is in C.1. Only information included in the appropriate numbered question will be considered by reviewers. Your application will be scored according to how well you address the requirements for each section of the Project Narrative.

- The number of points after each heading is the maximum number of points a review committee may assign to that section of your Project Narrative. Although scoring weights are not assigned to individual questions, each question is assessed in deriving the overall Section score.
- Any cost sharing proposed in your application will not be a factor in the evaluation of your response to the Evaluation Criteria.

SECTION A: Population of Focus and Statement of Need (10 points – approximately 1 page)

- Identify and describe your population(s) of focus and the geographic catchment area where services will be delivered that align with the intended population of focus of this program. Provide a demographic profile of the population of focus in the catchment area in terms of race, ethnicity, federally recognized tribe (if applicable), language, sex, gender identity, sexual orientation, age, and socioeconomic status.
- 2. Describe the extent of the problem in the catchment area, including service gaps, and document the extent of the need (i.e., current prevalence rates or incidence data) for the population(s) of focus identified in your response to A.1. Identify the source of the data.

SECTION B: Proposed Implementation Approach (30 points – approximately 5 pages not including Attachment 4 – Project Timeline)

1. Describe the goals and <u>measurable</u> objectives (see <u>Appendix F</u>) of the proposed project and align them with the Statement of Need described in A.2. Provide the following table:

Number of Unduplicated Individuals to be Served with Grant Funds					
Year 1	Year 2	Year 3	Year 4	Year 5	Total

- 2. Describe how you will implement all of the Required Activities in Section I. If you plan to use grant funds for infrastructure development, also describe how those funds will be used.
- 3. In **Attachment 4**, provide a chart or graph depicting a realistic timeline for the entire 5 years of the project period showing dates, key activities, and

responsible staff. These key activities must include the requirements outlined in Section I [NOTE: Be sure to show that the project can be implemented, and service delivery can begin as soon as possible and no later than four months after grant award. The timeline cannot be more than two pages and should be submitted in Attachment 4.] The recommendation of pages for this section does not include the timeline.

SECTION C: Proposed Evidence-Based Service/Practice (25 points approximately 2 pages)

- 1. Identify the Evidence-Based Practice(s) (EBPs), evidence-informed, and/or culturally promising practices that will be used. Discuss how each intervention chosen is appropriate for your population(s) of focus and the outcomes you want to achieve. Describe any modifications that will be made to the EBP(s) and the reason the modifications are necessary. If you are not proposing any modifications, indicate so in your response. interventions.
- 2. Describe how you will monitor and ensure fidelity of EBPs, evidence-informed and/or promising practices that will be implemented.

SECTION D: Staff and Organizational Experience (15 points – approximately 1 page)

- 1. Describe the experience of your organization with similar projects and/or providing services to the population(s) of focus for this NOFO. Identify other organization(s) that you will partner with in the proposed project. Describe their experience providing services to the population(s) of focus, and their specific roles and responsibilities for this project. If applicable, Letters of Commitment from each partner must be included **Attachment 1** of your application. If you are not partnering with any other organization(s), indicate so in your response.
- 2. Provide a complete list of staff positions for the project, including the Key Personnel (Project Director and Program Evaluator) and other significant personnel. Describe the role of each, their level of effort, and qualifications, to include their experience providing services to the population(s) of focus and familiarity with their culture(s) and language(s).

SECTION E: Data Collection and Performance Measurement (20 points – approximately 1 page)

1. Provide specific information about how you will collect the required data for this program and how such data will be utilized to manage, monitor, and enhance the program.

2. BUDGET JUSTIFICATION, EXISTING RESOURCES, OTHER SUPPORT (other federal and non-federal sources)

You must provide a narrative justification of the items included in your proposed budget, as well as a description of existing resources and other support you expect to receive for the proposed project. Other support is defined as funds or resources, whether federal, non-federal, or institutional, in direct support of activities through fellowships, gifts, prizes, in-kind contributions, or non-federal means. (This should correspond to Item #18 on your SF-424, Estimated Funding.) Other sources of funds may be used for unallowable costs, e.g., meals, sporting events, entertainment.

A link to a sample budget and narrative justification is included in <u>Appendix L</u> – Sample Budget and Justification. It is highly recommended that you use this sample budget format. Your budget must reflect the funding limitations/restrictions specified in Section IV.3. Specifically identify the items associated with these costs in your budget.

3. REVIEW AND SELECTION PROCESS

The Project Narratives of SAMHSA applications are peer-reviewed according to the evaluation criteria listed above.

Decisions to fund a grant are based on:

The strengths and weaknesses of the application as identified by peer reviewers. The results of the peer review are of an advisory nature.

The program office makes the final determination for funding based on the following;

- MAT-PDOA recipients who received funding in FY20 under TI-18-009 and in FY21 under TI-21-006 are not eligible to apply for this funding opportunity.
- When the individual award is over \$250,000, approval by the Center for Substance Abuse Treatment (CSAT) National Advisory Council;
- Availability of funds;
- Equitable distribution of awards in terms of geography (including urban, rural, and remote settings) and balance among populations of focus and program size:

- Submission of any required documentation that must be submitted prior to making an award;
- SAMHSA is required to review and consider any information about your organization that is in the Federal Award Performance and Integrity Information System (FAPIIS). In accordance with 45 CFR 75.212, SAMHSA reserves the right not to make an award to an entity if that entity does not meet the minimum qualification standards as described in section 75.205(a)(2). If SAMHSA chooses not to award a fundable application in accordance with 45 CFR 75.205(a)(2), SAMHSA must report that determination to the designated integrity and performance system accessible through the System for Award Management (SAM) [currently, FAPIIS]. You may review and comment on any information about your organization that a federal awarding agency previously entered. SAMHSA will consider your comments, in addition to other information in FAPIIS in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed as described in 45 CFR 75.205 HHS Awarding Agency Review of Risk by Applicants.

VI. FEDERAL AWARD ADMINISTRATION INFORMATION

1. FEDERAL AWARD NOTICES

You will receive an email from SAMHSA, via NIH's eRA Commons, that will describe the process for how you can view the general results of the review of your application, including the score that your application received.

If your application is approved for funding, a Notice of Award (NoA) will be emailed to the following: 1) the BO's email address identified in the Authorized Representative section email field on page 3 of the SF-424; and 2) the email associated with the Commons account for the Project Director (section 8 Item f on page 1 of the SF-424). Hard copies of the NoA will no longer be mailed via postal service. The NoA is the sole obligating document that allows you to receive federal funding for work on the grant project. Information about what is included in the NoA can be found at: https://www.samhsa.gov/grants/grants-management/notice-award-noa.

If your application is not funded, you will receive a notification from SAMHSA, via NIH's eRA Commons.

2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

If your application is funded, you must comply with all terms and conditions of the NoA. SAMHSA's standard terms and conditions are available on the SAMHSA website - . https://www.samhsa.gov/grants/grants-management/notice-award-noa/standard-terms-conditions. See <a href="https://www.samhsa.gov/grants/grants-management/notice-award-noa/standard-terms-noa/standard-

3. REPORTING REQUIREMENTS

In year 1 of the grant, you will be required to submit semi-annual programmatic reports that are due within 30 days of the reporting period. In years 2-5, annual progress reports on project performance will be due within 90 days of the end of each budget period. The report must discuss:

- Progress achieved in the project which should include qualitative and quantitative data (GPRA) to demonstrate programmatic progress in addressing quality care of under-resourced populations related to the Disparity Impact Statement (DIS);
- Barriers encountered, including barriers serving sub-populations;
- Efforts to overcome these barriers;
- Evaluation activities for tracking DIS efforts; and
- A revised quality improvement plan if the DIS does not meet quality of care requirements as stated in the DIS.

A final performance report must be submitted within 120 days after the end of the final budget period. The final performance report must be cumulative and report on all grant activities during the entire project period. Refer to <u>Section VI.3</u> for any program specific information on the frequency of reporting and any additional requirements.

Grants Management:

Successful applicants must also comply with the following standard grants management reporting requirements at https://www.samhsa.gov/grants/grants- management/reporting-requirements, unless otherwise noted in the NOFO or NoA.

VII. AGENCY CONTACTS

For program related and eligibility questions contact:

Fred Bamfo, DNP
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
(240) 276-2423
MAT-PDOA-C@samhsa.hhs.gov

For fiscal/budget related questions contact:

Office of Financial Resources, Division of Grants Management Substance Abuse and Mental Health Services Administration (240) 276-1400 FOACSAT@samhsa.hhs.gov

For grant review process and application status questions contact:

Angela Houde
Office of Financial Resources, Division of Grant Review
Substance Abuse and Mental Health Services Administration
(240) 276-1091
Angela.Houde@samhsa.hhs.gov

Appendix A – Application and Submission Requirements

1. GET REGISTERED

You are required to complete four (4) registration processes:

- 1.1) Dun & Bradstreet Data Universal Numbering System (DUNS number) Please review the information below on the DUNS number transitioning to a new Unique Entity Identifier (UEI) effective April 2022.
- 1.2) System for Award Management (SAM);
- 1.3) Grants.gov; and
- 1.4) eRA Commons.

If this is your first time submitting an application, you must complete all four registration processes until the new UEI becomes active April 4, 2022. Please take note of the timing for these registrations.

If you have already completed registrations for DUNS, SAM, and Grants.gov, you need to ensure that your accounts are still active, and then register in **eRA Commons** (see 1.4).

You must register in eRA Commons and receive a Commons Username in order to have access to electronic submission, receive notifications on the status of your application, and retrieve grant information.

WARNING: If your organization is not registered and does not have an active eRA Commons PI/PD account by the deadline, the application will not be accepted. <u>No</u> exceptions will be made.

1.1 Dun & Bradstreet Data Universal Numbering System (DUNS) Registration

Starting April 4, 2022, the Data Universal Numbering System (DUNS) will be replaced by a Unique Entity Identifier (SAM) created in SAM.gov. For information on the transition, see https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/iae-systems-information-kit/unique-entity-identifier-update.

To obtain a DUNS number, access the Dun and Bradstreet website at: http://www.dnb.com or call 1-866-705-5711. To expedite the process, let Dun and Bradstreet know that you are a public/private nonprofit organization getting ready to submit a federal grant application. The DUNS number you use on your application must be registered and active in the System for Award Management.

After April 4, 2022, you will obtain a UEI through sam.gov. If your organization is registered in SAM.gov, your Unique Entity Identifier (SAM) has already been assigned and is viewable in SAM.gov. This includes inactive registrations. The Unique Entity Identifier is currently located below the DUNS Number on your entity registration record. You must be signed in to your SAM.gov account to view entity records.

1.2 System for Award Management Registration

You must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information during the period of time your organization has an active federal award or an application under consideration by an agency (unless you are an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), has an exception approved by the agency under 2 CFR § 25.110(d)). To create a SAM user account, Register/Update your account, and/or Search Records, go to https://www.sam.gov. It takes 7-10 business days for a new SAM entity registration to become active.

It is important to initiate this process well before the application deadline. You will receive an email alerting you when your registration is active. You will continue to register in SAM.gov using the DUNS number assigned by Dun and Bradstreet until April 4, 2022.

It is also highly recommended that you renew your account prior to the expiration date. **SAM information must be active and up-to-date and should be updated at least every 12 months to remain active (for both recipients and sub-recipients).** Once you update your record in SAM, **it will take 48 to 72 hours to complete the validation** processes. Grants.gov rejects electronic submissions from applicants with expired registrations.

If your SAM account expires, the renewal process requires the same validation with IRS and DoD (Cage Code) as a new account requires.

1.3 Grants.gov Registration

<u>Grants.gov</u> is an online portal for submitting federal grant applications. It requires a one-time registration to submit applications. While Grants.gov registration is a one-time only registration process, it consists of multiple sub-registration processes (i.e., DUNS number and SAM registrations) before you can submit your application. [Note: eRA Commons registration is separate but can be done concurrently. See 1.4.]. You can register to obtain a Grants.gov username and password at http://www.grants.gov/web/grants/register.html.

If you have already completed Grants.gov registration and ensured your **Grants.gov** and **SAM** accounts are up-to-date and/or renewed, go to the eRA Commons registration steps noted below. If this is your first time submitting an application through Grants.gov, registration information can be found at the Grants.gov "Applicants" tab.

The person submitting your application must be properly registered with Grants.gov as the Authorized Organization Representative (AOR) for the specific DUNS number cited on the SF-424 (first page). See the Organization Registration User Guide for details at the following Grants.gov link: http://www.grants.gov/web/grants/applicants/organization-registration.html.

1.4 eRA Commons Registration

eRA Commons is an online data platform managed by NIH that allows applicants, award recipients, and federal staff to securely share, manage, and process grant-related information. It is strongly recommended that you start the eRA Commons registration process at least six (6) weeks prior to the application due date.

Organizations applying for SAMHSA funding must register in eRA Commons. This is a one-time registration separate from Grants.gov registration. Note: Grants.gov and eRA Commons Registration may occur concurrently. In addition to the organization registration, the BO named in the Authorized Representative section field on page 4 of the SF-424 and the Project Director details entered in the Applicant Information item f on page 2 of the SF-424 (Name and contact information of the person to be contacted on matters involving this application) must have accounts in eRA Commons and receive a Commons ID in order to have access to electronic submission and retrieval of application/grant information. If your organization is not registered and does not have an active eRA Commons PI account by the deadline, the application will not be accepted.

For organizations registering with eRA Commons for the first time, the BO named in the Authorized Representative section of the SF-424 must complete the online <u>Institution</u> <u>Registration Form</u>. Instructions on how to complete the online Institution Registration Form is provided on the eRA Commons Online Registration Page.

[Note: You must have a valid and verifiable DUNS number to complete the eRA Commons registration.]

After the BO named as the Authorized Representative completes the online Institution Registration Form and clicks Submit, the eRA Commons will send an e-mail notification from era-notify@mail.nih.gov with the link to confirm the email address. Once the e-mail address is verified, the registration request will be reviewed and confirmed via email. If your request is denied, the representative will receive an email detailing the reason for the denial. If the request is approved, the BO will receive an email with a Commons

User ID for the Signing Official account ('SO') role. The representative will receive a separate email pertaining to this SO account containing a temporary password to be used for the first-time log in. The representative will need to log into Commons with the temporary password, at which time the system will provide prompts to change the temporary password to one of their choosing. Once the BO/SO signs the registration request, the organization will be active in Commons. The BO/SO can then create additional accounts for the organization as needed. Organizations can have multiple user accounts with the SO role, and any user with the SO role will be able to create and maintain additional accounts for the organization's staff, including accounts for those designated as Project Director/Principal Investigator (PD/PI) and other Signing Officials.

Important: The eRA Commons requires organizations to identify at least one BO/SO, who is the BO entered in the Authorized Representative section on the SF-424, and a PD/PI in order to submit an application. The primary BO/SO must create the account for the PD/PI listed as the person to contact regarding the application on page 2 of the SF-424 assigning that person the 'PI' role in Commons. Note that you must also enter the PD/PI's Commons Username into the 'Applicant Identifier' field of the SF-424 document (Line 4).

You can find additional information about the eRA Commons registration process at https://era.nih.gov/reg_accounts/register_commons.cfm.

2. WRITE AND COMPLETE APPLICATION

SAMHSA strongly encourages you to sign up for Grants.gov email notifications regarding this NOFO. If the NOFO is cancelled or modified, individuals who sign up with Grants.gov for updates will be automatically notified.

2.1 Obtaining Paper Copies of Application Materials

If your organization has difficulty accessing high-speed internet and cannot download the required documents, you may request a paper copy of the application materials. Call the Division of Grant Review at 240-276-1199 for additional information on obtaining paper copies.

2.2 Required Application Components

After downloading and retrieving the required application components and completing the registration processes, it is time to write and complete your application. All files uploaded with the Grants.gov application **MUST** be in **Adobe PDF** file format. Directions for creating PDF files can be found on the Grants.gov website. See Appendix B for all application formatting and validation requirements.

Standard Application Components

Applications must include the following required application components listed in the table below. This table consists of a full list of standard application components, a description of each required component, and where you can find each document.

#	Standard Application Components	Description	Where to Find Document
1	SF-424 (Application for Federal Assistance) Form	This form must be completed by applicants for all SAMHSA grants. The names and contact information for Project Director (PD) and Business Official (BO) are required for SAMHSA applications, and are to be entered on the SF-424 form.	Grants.gov/forms
		 The PD must have an eRA Commons account: the PD's Commons Username must be entered in field 4. Applicant Identifier; and the PD's name, phone number and email address must be entered in Section 8. APPLICANT INFORMATION: item f. Name and contact information of person to be contacted on matters involving this application. 	
		 The BO name, title, email address and phone number must be entered in the Authorized Representative section fields on page four of the SF 424. The organization mailing address is required in section 8. APPLICANT INFORMATION item d. Address. 	
		All SAMHSA Notices of Award (NoAs) will be emailed by SAMHSA via NIH's eRA Commons to the Project Director/Principal Investigator (PD/PI), and the Signing Official/Business Official (SO/BO).	
2	SF-424 A (Budget Information – Non- Construction Programs) Form	Use SF-424A. Fill out Sections A, B, D and E of the SF-424A. Section C should only be completed if applicable. It is highly recommended that you use the budget template.	Grants.gov/forms
3	Project/Performance Site Location(s) Form	The purpose of this form is to collect location information on the site(s) where work funded under this grant announcement will be performed.	Grants.gov/forms
4	Project Abstract Summary	It is recommended the abstract is no more than one page. It should include the project name, population(s) to be served (demographics and clinical characteristics), strategies/interventions,	

#	Standard Application Components	Description	Where to Find Document
		project goals and measurable objectives, including the number of people to be served annually and throughout the lifetime of the project, etc. In the first five lines or less of your abstract, write a summary of your project that can be used, if your project is funded, in publications, reports to Congress, or press releases.	
5	Project Narrative Attachment	The Project Narrative is your response to the Evaluation Criteria found at Section V.1 of this NOFO. It cannot be longer than 10 pages. You must attach the Project Narrative file (Adobe PDF format only) inside the Project Narrative Attachment Form.	
6	Budget Justification and Narrative Attachment	You must include a detailed Budget Narrative in addition to Budget Form SF-424A. In preparing the budget, adhere to any existing federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. The budget justification and narrative must be submitted as file "BNF" when you submit your application into Grants.gov.	SAMHSA Website
7	SF-424 B (Assurances for Non-Construction) Form	You must read the list of assurances provided on the SAMHSA website and check the box marked 'I Agree' before signing the first page (SF-424) of the application.	SAMHSA Website
8	Disclosure of Lobbying Activities (SF-LLL) Form	Federal law prohibits the use of appropriated funds for publicity or propaganda purposes or for the preparation, distribution, or use of the information designed to support or defeat legislation pending before Congress or state legislatures. You must sign and submit this form, if applicable.	Grants.gov/forms
9	Other Attachments Form	Refer to the Supporting Documents below. Use the Other Attachments Form to attach all required additional/supporting documents listed in the table below.	

Supporting Documents

In addition to the Standard Application Components listed above, the following supporting documents are necessary for the review of your application. Supporting documents must be attached to your application. For each of the following

application components, attach each document (Adobe PDF format only) using the Other Attachments Form in ASSIST, Workspace, or other S2S provider.

#	Supporting Documents	Description	Where to Find Document
1	HHS 690 Form	Every grant applicant must have a completed HHS 690 form (PDF 291 KB) on file with the Department of Health and Human Services.	SAMHSA Website
2	Charitable Choice Form SMA 170 (Attachment 9)	See Section IV-1 of the NOFO to determine if you are required to submit Charitable Choice Form SMA 170. If you are, you can upload this form to Grants.gov when you submit your application.	SAMHSA Website
3	Biographical Sketches and Job Descriptions (Attachment 5)	See Appendix G of this document for additional instructions for completing these sections. Formatting requirements outlined in Appendix B are not applicable for these documents.	Appendix G of this document.
4	Confidentiality and SAMHSA Participant Protection/Human Subjects (Attachment 7)	See the NOFO or requirements related to confidentiality, participant protection, and the protection of human subject's regulations.	NOFO: See Appendix D
5	Additional Documents in the NOFO	The NOFO will indicate the attachments you need to include in your application.	NOFO: Section IV.

2.3 Additional Documents for Submission (SAMHSA Website)

You will find additional materials you will need to complete your application on the SAMHSA website at http://www.samhsa.gov/grants/applying/forms-resources.

3. SUBMIT APPLICATION

3.1 Electronic Submission (eRA ASSIST, Grants.gov Workspace, or other S2S provider)

After completing all required registration and application requirements, SAMHSA requires applicants to **electronically submit** using eRA ASSIST, Grants.gov Workspace, or another system to system (S2S) provider. Information on each of these options is below:

- 1) ASSIST The Application Submission System and Interface for Submission Tracking (ASSIST) is an NIH sponsored online interface used to prepare applications using the SF424 form set, submit electronically through Grants.gov to SAMHSA and other participating agencies, and track grant applications. [Note: ASSIST requires an eRA Commons ID to access the system]
- 2) Grants.gov Workspace You can use the shared, online environment of the Grants.gov Workspace to collaboratively work on different forms within the application.

The specific actions you need to take to submit your application will vary by submission method as listed above. The steps to submit your application are as follows:

To submit to Grants.gov using ASSIST: <u>eRA Modules, User Guides, and Documentation</u> | Electronic Research Administration (eRA)

To submit to Grants.gov using the Grants.gov Workspace:

http://www.grants.gov/web/grants/applicants/workspace-overview.html

Regardless of the option you use, your application will be subject to the same registration requirements, completed with the same data items, routed through Grants.gov, validated against the same agency business rules, assembled in a consistent format for review consideration, and tracked in eRA Commons. All applications that are successfully submitted must be validated by Grants.gov before proceeding to the NIH eRA Commons system and validations.

3.2 Waiver from Electronic Submission

SAMHSA will not accept paper applications except under very special circumstances. If you need special consideration, SAMHSA must approve the waiver of this requirement in advance.

If you do not have the technology to apply online, or your physical location has no Internet connection, you may request a waiver of electronic submission. You must send a written request to the Division of Grant Review at least 15 calendar days before the application due date.

Direct any questions regarding the submission waiver process to the Division of Grant Review at 240-276-1199.

3.3 Deadline

On-time submission requires that electronic applications be error-free and made available to SAMHSA for processing from the NIH eRA system on or before the application due date and time. Applications must be submitted to and validated successfully by Grants.gov and eRA Commons no later than 11:59 PM Eastern Time on the application due date. Applications submitted in Grants.gov after the application due date will not be considered for review.

You are strongly encouraged to allocate additional time prior to the submission deadline to submit your application and to correct errors identified in the validation process. You are also encouraged to check the status of your application submission to determine if the application is complete and error-free.

3.4 Resources for Assistance

If you encounter problems when submitting your application in Grants.gov, you must attempt to resolve them by contacting the Grants.gov Service Desk at the following:

- By e-mail: support@grants.gov
- By phone: (toll-free) 1-800-518-4726 (1-800-518-GRANTS). The Grants.gov Contact Center is available 24 hours a day, 7 days a week, excluding federal holidays.

Make sure you receive a case/ticket/reference number that documents the issues/problems with Grants.gov.

Additional support is also available from the NIH eRA Service desk at:

- By e-mail: http://grants.nih.gov/support/index.html
- By phone: 301-402-7469 or (toll-free) 1-866-504-9552. (press menu option 6 for SAMHSA). The NIH eRA Service desk is available Monday Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

If you experience problems accessing or using ASSIST (see below), you can:

- Access the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist/
- Or contact the NIH eRA Service Desk

SAMHSA highly recommends that you submit your application 24-72 hours before the submission deadline. Many submission issues can be fixed within that time and you can attempt to re-submit.

4. AFTER SUBMISSION

4.1 System Validations and Tracking

After you complete and comply with all registration and application requirements and submit your application, the application will be validated by Grants.gov. You will receive a notification that your application is being processed. You will receive two additional emails from Grants.gov within the next 24-48 hours (one notification email will confirm receipt of the application in Grants.gov, and the other notification email will indicate that the application was either successfully validated by the Grants.gov system or rejected due to errors). It is important that you retain this Grants.gov tracking number. **Receipt of the Grants.gov tracking number is the only indication that Grants.gov has successfully received and validated your application.** If you do not receive a Grants.gov tracking number, you may want to contact the Grants.gov help desk for assistance (see Resources for Assistance in Section 3.4).

If Grants.gov identifies any errors and rejects your application with a "Rejected with Errors" status, you must address all errors and resubmit. If no problem is found, Grants.gov will allow the eRA system to retrieve the application and check it against its own agency business rules (eRA Commons Validations). If you use ASSIST to complete your application, you can validate your application and fix errors before submission.

After you successfully submit your application through Grants.gov, your application will go through eRA Commons validations. If no errors are found, the application will be assembled in eRA Commons. At this point, you can view your application in eRA commons. It will then be forwarded to SAMHSA as the receiving institution for further review.

If errors are found during eRA Commons validation, you will receive a System Error and/or Warning notification regarding the problems found in the application (see 4.2 below). You must take action to make the required corrections and resubmit the application through Grants.gov before the application due date and time. Do not assume that if your application passes the grants.gov validations that it will successfully pass eRA validations and will be received by SAMHSA. You must check your application status in eRA Commons to ensure that no errors were identified. It is critical that you allow for sufficient time to resubmit the application if errors are detected.

You are responsible for viewing and tracking your applications in the eRA Commons after submission through Grants.gov to ensure accurate and successful submission. Once you can access your application in the eRA Commons, be sure to review it carefully as this is what reviewers will see.

4.2 eRA Commons: Warning vs. Error Notifications

You may receive a System Warning and/or Error notification after submitting an application. Take note that there is a distinction between System Errors and System Warnings.

Warnings – If you receive a <u>Warning</u> notification after the application is submitted, you are <u>not required to resubmit</u> the application. The reason for the Warning will be identified in the notification. It is at your discretion to choose to resubmit, but if the application was successfully received, it does not require any additional action.

Errors – If you receive an <u>Error</u> notification after the applications is submitted, you <u>must</u> <u>correct and resubmit the application</u>. The word Error is used to characterize any condition which causes the application to be deemed unacceptable for further consideration.

4.3 System or Technical Issues

If you encounter a system error that prevents you from completing the application submission process on time, the BO from your organization will receive an email notification from eRA Commons. SAMHSA highly recommends contacting the eRA Service Desk and submitting a web ticket to document your good faith attempt to submit your application and determining next steps. See Section 3.4 for more information on contacting the eRA Service Desk.

4.4 Resubmitting a Changed/Corrected Application

If SAMHSA does not receive your application by the application due date as a result of a failure in the SAM, Grants.gov, or NIH's eRA Commons systems, you must contact the Division of Grant Review within one-business day after the official due date at:dgr.applications@samhsa.hhs.gov and provide the following:

 A case number or email from SAM, Grants.gov, and/or NIH's eRA system that allows SAMHSA to obtain documentation from the respective entity for the cause of the error.

SAMHSA will consider the documentation to determine <u>if</u> you followed Grants.gov and NIH's eRA requirements and instructions, met the deadlines for processing paperwork within the recommended time limits, met NOFO requirements for submission of electronic applications, and made no errors that caused submission through Grants.gov or NIH's eRA to fail. No exceptions for submission are allowed when user error is involved. Note that system errors are extremely rare.

[Note: When resubmitting an application after revisions have been made, ensure that the <u>Project Title is identical to the Project Title in the originally submitted application</u> (i.e., no extra spacing) as the Project Title is a free-text form field.] In addition, check the Changed/Corrected Application box in #1.

Appendix B - Formatting Requirements and System Validation

1. SAMHSA FORMATTING REQUIREMENTS

SAMHSA's goal is to review all applications submitted for grant funding. However, this goal must be balanced against SAMHSA's obligation to ensure equitable treatment of applications. For this reason, SAMHSA has established certain formatting requirements for its applications. See below for a list of formatting requirements required by SAMHSA:

- Text must be legible. Pages must be typed in black, single-spaced, using a font of Times New Roman 12, with all margins (left, right, top, bottom) at least one inch each. You may use Times New Roman 10 only for charts or tables.
- You must submit your application and all attached documents in Adobe PDF format, or your application will not be forwarded to eRA Commons and will not be reviewed. See Section 3 below for more details on PDF requirements.
- To ensure equity among applications, the 10-page limit for the Project Narrative cannot be exceeded. If an application exceeds the 10-page limit, the application will not be reviewed.
- Black print should be used throughout your application, including charts and graphs (no color).
- If you are submitting more than one application under the same announcement number, you must ensure that the Project Title in Field 15 of the SF-424 is unique for each submission.

2. GRANTS.GOV FORMATTING AND VALIDATION REQUIREMENTS

- Grants.gov allows the following list of UTF-8 characters when naming your attachments: A-Z, a-z, 0-9, underscore, hyphen, space, and period. Other UTF-8 characters should not be used as they will not be accepted by NIH's eRA Commons, as indicated in item #9 in the table below.
- Scanned images must be scanned at 150-200 dpi/ppi resolution and saved as a PDF file. Using a higher resolution setting or different file type will result in a larger file size, which could result in rejection of your application.

 Any files uploaded or attached to the Grants.gov application must be PDF file format and must contain a valid file format extension in the filename. In addition, the use of compressed file formats such as ZIP, RAR or Adobe Portfolio will not be accepted.

3. era commons formatting and validation requirements

The following are formatting requirements and system validations required by eRA Commons and will result in errors if not met. The application <u>must be 'error free'</u> to be processed through the eRA Commons. There may be additional validations which will result in Warnings but these <u>will not</u> prevent the application from processing through the submission process. (See Appendix A, Section 4.2)

ASSIST File Formatting Requirements

The eRA system contains file formatting requirements for uploading documents in ASSIST. The only accepted file type for submission is PDF and each file may be no larger than 6 MB. Fillable forms must be 'flattened' and saved as a PDF prior to upload. Adobe Portfolio file types will not be accepted.

Files for Upload to ASSIST must be:

- ☑ PDF Format
- ☑ Under 6MB in File Size
- ☑ 8.5 x 11 Page Size
- ☑ Flat (No Fillable/Editable Fields)

Files must **NOT** contain:

- ☑ Password-Protection
- ☑ Live hyperlinks (only plain text URLs)
- Bookmarks or Signature Boxes
- ☑ A filename exceeding 50 Characters (including spaces)

Flatten Fillable Forms Prior to Upload in ASSIST

A completed fillable form (an electronic document that can be filled out and edited digitally—also called fillable, dynamic, or interactive forms) should not only be saved as a PDF; it must also be flattened to remove the interactive fields so that the final answers

are saved. Flattening a form is not the same as "locking" it; locking a form restricts access to editing, printing, and copying the document.

Flattening a PDF document:

- **Keeps form values permanent.** When an interactive PDF is uploaded or emailed, every field remains open to accidental or deliberate revision. Flattening the form ensures that only the completed version of the form is visible.
- Removes values on drop down lists. A flattened document will show only the selected text or value, no other values and options are shown and there is no indication that options were present.
- **Simplifies the PDF.** Interactive forms are larger than normal files, which may prevent upload for submission. Flattening reduces the file size which makes it easier to render and view.

To flatten a file, follow the steps below.

- 1. Ensure that the form is completed, and the information is correct. Go to the print settings by selecting **File > Print**.
- 2. On the pull-down menu of printer options, choose Adobe PDF or Microsoft Print to PDF, then click OK.
- 3. After clicking OK, a pop-up will open with options to save the PDF. Be sure to select a specific location to save the document where it can easily be found and give it a unique file name. Use a file name that clearly differentiates the completed form from the original fillable form. File names cannot exceed 50 characters.
- The flattened form should appear in the new location with the new file name.
 Open it to check once more for any changes and to confirm that the conversion worked.

If you do not adhere to these requirements, you will receive an email notification from era-notify@mail.nih.gov to take action and adhere to the requirements so that your application can be processed successfully. It is highly recommended that you submit your application 24-72 hours before the submission deadline to allow for sufficient time to correct errors and resubmit the application. If you experience any system validation or technical issues after hours on the application due date, contact the eRA Service Desk and submit a Web ticket to document your good faith attempt to submit your application.

eRA Commons Validation Table

The following table shows formatting requirements and system validations required by eRA Commons and will result in errors if not met.

eRA Validations	eRA Error Messages
#1: Applicant Identifier (Item 4 on the SF-424):	
The PD/PI Credentials must be provided	The Commons Username must be provided in the Applicant Identifier field for the PD/PI.
Username provided must be a valid Commons account	The Commons Username provided in the Applicant Identifier is not a recognized Commons account.
Username must be affiliated with the organization submitting the application and or have the PI role	The Commons account provided in the Applicant Identifier field for the PD/PI is either not affiliated with the applicant organization or does not hold the PI role. Check with your Commons Account Administrator to make sure your account affiliation and roles are set-up correctly.
#2. The DUNS number provided must include valid characters (9 or 13 numbers with or without dashes)	The DUNS number provided has invalid characters (other than 9 or 13 numbers) after stripping of dashes
#3. The documentation (forms) required for the NOFO must be submitted	The format of the application does not match the format of the NOFO. Contact the eRA Service Desk for assistance.
#4 If a change or correction is made to address an error, "Changed/Corrected" must be selected. (Item #1 on the SF-424). Refer to Appendix A II-4.4 for more information on resubmission criteria.	This application has been identified as a duplicate of a previous submission. The 'Type of Submission' should be set to Changed/Corrected if you are addressing errors/warnings.
#5. The application cannot exceed 1.2GB.	The application did not follow the agency-specific size limit of 1.2 GB. Resize the application to be no larger than 1.2 GB before submitting.
#6. The correct Notice of Funding Opportunity (NOFO) number must be provided	The Funding Opportunity Announcement number does not exist.

eRA Validations	eRA Error Messages
#7. All documents and attachments must be submitted in PDF format.	"The <attachment> attachment is not in PDF format. All attachments must be provided to the agency in PDF format with a .pdf extension. Help with PDF attachments can be found at http://grants.nih.gov/grants/ElectronicReceipt/pdf g uidelines.htm."</attachment>
#8. All attachments must comply with the following formatting requirements: PDF attachments cannot be empty (0 bytes).	The {attachment} attachment was empty. PDF attachments cannot be empty, password protected or encrypted.
All PDF attachments cannot have Meta data missing, cannot be encrypted, password protected or secured documents.	The <attachment> attachment contained formatting or features not currently supported by NIH: <condition returned="">.</condition></attachment>
The size of PDF attachments cannot be larger than 8.5 x 11 inches (horizontally or vertically). [Note: It is recommended that you limit the size of attachments to 35 MB.]	Filename <file> cannot be larger than U.S. standard letter paper size of 8.5 x 11 inches. See the PDF guidelines at http://grants.nih.gov/grants/ElectronicReceipt/pdfguidelines.htm</file>
PDF attachments must have a valid file name. Valid file names must include the following UTF-8 characters: A-Z, a-z, 0-9, underscore (_), hyphen (-), space, period.	The <attachment> attachment filename is invalid. Valid filenames may only include the following characters: A-Z, a-z, 0-9, underscore (_), hyphen (-), space, or period. No special characters (including brackets) can be part of the filename.</attachment>
#9. The email addresses for the Contact Person (SF-424 Section F) and the Authorized Representative (SF-424 below Section 21) must contain a '@', with at least 1 and at most 64 chars preceding and following the '@'. Control characters (ASCII 0 through 31 and 127), spaces and special chars < > ()[];: are not valid.	The submitted e-mail address for the person to be contacted {email address}, is invalid. Must contain a '@', with at least 1 and at most 64 chars preceding and following the '@'. Control characters (ASCII 0 through 31 and 127), spaces and special chars < > ()[];: are not valid.
#10. Congressional district code of applicant (after truncating) must be valid. (SF-424, item 16 a and b)	Congressional district < Congressional District > is invalid. To locate your district, visit http://www.house.gov/

Budget Errors				
eRA Validations	eRA Error Messages			
SF424-A: Section A – Budget Summary The total fields at the end of rows or at the bottom of columns must equal the sum of the elements for that row or column	Ensure that the sum of Grant Program Function or Activity (a) elements entered equals the total amounts in the Total field			
SF424-A: Section B – Budget Categories The Total in Section B (Column 5 - Row k) must equal the Total in Section A – Budget Summary: (Row 5, Column g).	Ensure that the TOTALS Total (row k, column 5) equals the Budget Summary Totals in section A, row 5 column g.			
SF424-A: Section D – Forecasted Cash Needs The Federal Total for the 1st Year (Line 13) must equal the Total in Section A (Row 5, Column g)	Ensure that the Federal Total for 1st year, in Section D- Forecasted Needs equals the Section A, New or Revised Budget Federal Totals (e-5) amount.			
The Non-Federal Total for 1st Year sum must equal Estimated Unobligated Funds Non-Federal Totals in Section A (d-5) + New or Revised Budget Non-Federal Totals (f-5)	Ensure that the Non-Federal Total for 1st year equals the sum of Estimated Unobligated Funds Non-Federal Totals (d-5) and New or Revised Budget Non-Federal Totals (f-5) on Section A.			
The Total for 1st Year TOTAL in Section D must equal the Totals Total (Column 5, Row G) in Section A	Ensure that the Forecasted Cash Needs: 15. TOTAL equals to SECTION A – Budget Summary: 5. Totals Total (g).			
SF424-A: Section E – Budget Estimates of Federal Funds Needed for Balance of The Project				
The number of budget years/periods must match the span of the project. The number of years in the project period in Block 17 on the SF-424 must align with the future funding periods.	Ensure that the project period years on the SF 424 block 17 matches the provided budget periods in the SF-424A. Enter data for the first budget period in Section D and enter future budget periods in Section E.			

Appendix C – General Eligibility Information

Determining whether you are eligible to apply for and receive a SAMHSA grant is very important. If you are not legally eligible for a specific funding opportunity, you would spend considerable time and money completing the application process when you cannot receive the grant.

There are many types of organizations generally eligible to apply for SAMHSA funding opportunities. However, eligibility is strictly tied to the statutory authority governing this grant. Please be sure to double check the NOFO for eligibility. Eligibility for this NOFO may include the following:

Government Organizations

State governments and territories

County governments

City or township governments

Special district governments

Native American tribal governments (federally recognized)

Native American tribal governments (other than federally recognized)

State-Recognized Tribes

Other Tribal Entities

Tribal organizations

Consortia of tribes or tribal organizations

Urban Indian Organizations

Education Organizations

Independent school districts

Public and state-controlled institutions of higher education

Private institutions of higher education

Education agencies/authorities serving children and youth residing in federally recognized American Indian/Alaska Native (AI/AN) tribes

Nonprofit Organizations

Nonprofits having a 501(c)(3) status with the Internal Revenue Service (IRS), other than institutions of higher education

Nonprofits that do not have a 501(c)(3) status with the IRS, other than institutions of higher education, including entities with 501(c)(4) status (civic leagues, social welfare organizations, and local associations of employees) and 501(c)(5) status (labor organizations)

Please note: For-profit organizations and foreign entities are not eligible to apply for SAMHSA grants.

Appendix D – Confidentiality and SAMHSA Participant Protection/Human Subjects Guidelines

CONFIDENTIALITY AND PARTICIPANT PROTECTION:

It is important to have safeguards protecting individuals from risks associated with their participation in SAMHSA projects. As part of Attachment 7 of the application, all applicants (including those who plan to obtain Institutional Review Board (IRB) approval) must address the elements below. If some elements are not applicable to the proposed project, explain why the element(s) is not applicable. In addition to addressing these elements, you will need to determine if the section below titled "Protection of Human Subjects Regulations" applies to your project. If so, you must submit the required documentation as described below.

1. Protect Clients and Staff from Potential Risks

- Identify and describe the foreseeable physical, medical, psychological, social, and legal risks or potential adverse effects participants may be exposed to because of the project.
- Identify and describe the foreseeable physical, medical, psychological, social, and legal risks or potential adverse effects staff may be exposed to as a result, of the project.
- Describe the procedures you will follow to minimize or protect participants and staff against potential risks, including risks to confidentiality.
- Identify your plan to provide guidance and assistance in the event there are adverse effects to participants and/or staff.

2. Fair Selection of Participants

- Explain how you will recruit and select participants.
- Identify any individuals in the geographic catchment area where services will be delivered who will be excluded from participating in the project and explain the reasons for this exclusion.

3. Absence of Coercion

If you plan to compensate participants, state how participants will be awarded incentives (e.g., gift cards, bus passes, gifts, etc.) If you have included funding for incentives in your budget, you must address this item. (A recipient or treatment or prevention provider may provide up to \$30 non-cash incentive to individuals to participate in required data collection follow up. This amount may be paid for participation in each required follow-up interview.)

- Provide justification that the use of incentives is appropriate, judicious, and conservative and that incentives do not provide an "undue inducement" that removes the voluntary nature of participation.
- Describe how you will inform participants that they may receive services even if they chose to not participate in or complete the data collection component of the project.

4. Data Collection

- Identify from whom you will collect data (e.g., participants, family members, teachers, others).
- Describe the data collection procedures and specify the sources for obtaining data (e.g., school records, interviews, psychological assessments, questionnaires, observation, or other sources). Identify what type of specimens (e.g., urine, blood) will be used, if any. State if the specimens will be used for purposes other than evaluation.
- In **Attachment 2**, "Data Collection Instruments/Interview Protocols," you **must** provide copies of all available data collection instruments and interview protocols that you plan to use (unless you are providing the web link to the instrument(s)/protocol(s)).

5. Privacy and Confidentiality

- Explain how you will ensure privacy and confidentiality. Describe:
 - Where data will be stored.
 - Who will have access to the data collected, and
 - How the identity of participants will be kept private, for example, using a coding system on data records, limiting access to records, or storing identifiers separately from data.
- NOTE: Recipients must maintain the confidentiality of alcohol and drug misuse client records according to the provisions of Title 42 of the Code of Federal Regulations, Part II, Subpart B.

6. Adequate Consent Procedures

- Include, as appropriate, sample consent forms that provide for:
 - 1. informed consent for participation in service intervention;
 - 2. informed consent for participation in the data collection component of the project; and

- 3. informed consent for the exchange (releasing or requesting) of confidential information.
- The sample forms must be included in **Attachment 3**, "**Sample Consent Forms**", of your application. If needed, give English translations.
- Explain how you will obtain consent for youth, the elderly, people with limited reading skills, and people who do not use English as their first language.
 Describe how the consent will be documented. For example: Will you read the consent forms? Will you ask prospective participants questions to be sure they understand the forms? Will you give them copies of what they sign?

NOTE: The consent forms should never imply that the participant waives or appears to waive any legal rights. The forms should also not imply that individuals cannot end involvement with the project or that your project or its agents will be released from liability for negligence.

7. Risk/Benefit Discussion

 Discuss why the risks you have identified in Element 1. Protect Clients and Staff from Potential Risks are reasonable compared to the anticipated benefits to participants involved in the project.

PROTECTION OF HUMAN SUBJECTS REGULATIONS

SAMHSA expects that most recipients funded under this announcement will not have to comply with the Protection of Human Subjects Regulations (45 CFR 46), which requires Institutional Review Board (IRB) approval. However, in some instances, the applicant's proposed project may meet the regulation's criteria for research involving human subjects. Although IRB approval is not required at the time of award, you are required to provide the documentation below prior to enrolling participants into your project.

In addition to the elements above, applicants whose projects must comply with the Human Subjects Regulations must:

- Describe the process for obtaining IRB approval for your project.
- Provide documentation that an Assurance of Compliance is on file with the Office for Human Research Protections (OHRP).
- Provide documentation that IRB approval has been obtained for your project prior to enrolling participants.

General information about Human Subjects Regulations can be obtained through OHRP at http://www.hhs.gov/ohrp or (240) 453-6900. SAMHSA–specific questions should be directed to the program contact listed in Section VII of this announcement.

Appendix E – Developing Goals and Measurable Objectives

To be able to effectively evaluate your project, it is critical that you develop realistic goals and <u>measurable</u> objectives. This appendix provides information on developing goals and objectives for use in your Project Narrative. It also provides examples of well-written goals and measurable objectives.

GOALS

<u>Definition</u> – a goal is a broad statement about the long-term expectation of what should happen because of your program (the desired result). It serves as the foundation for developing your program objectives. Goals should align with the statement of need that is described. Goals should only be one sentence.

The characteristics of effective goals include:

- Goals address outcomes, not how outcomes will be achieved.
- Goals describe the behavior or condition in the community expected to change.
- Goals describe who will be affected by the project.
- Goals lead clearly to one or more measurable results.
- Goals are concise.

Examples

Unclear Goal	Critique	Improved Goal
Increase the substance misuse and HIV/AIDS prevention capacity of the local school district	This goal could be improved by specifying an expected program effect in reducing a health problem	Increase the capacity of the local school district to reduce high-risk behaviors of students that may contribute to substance misuse and/or HIV/AIDS
Decrease the prevalence of marijuana, alcohol, and prescription drug use among youth in the community by increasing the number of schools that implement effective policies, environmental change, intensive training of teachers, and educational approaches to address high-risk behaviors, peer pressure, and tobacco use.	This goal is not concise	Decrease youth substance use in the community by implementing evidence-based programs within the school district that address behaviors that may lead to the initiation of use.

OBJECTIVES

<u>Definition</u> – Objectives describe the results to be achieved and the manner in which they will be achieved. Multiple objectives are generally needed to address a single goal. Well-written objectives help set program priorities and targets for progress and accountability. It is recommended that you avoid verbs that may have vague meanings to describe the intended outcomes, like "understand" or "know" because it may prove difficult to measure them. Instead, use verbs that document action, such as: "By the end of 2020, 75 percent of program participants will be *placed* in permanent housing. To be effective, objectives should be clear and leave no room for interpretation.

SMART is a helpful acronym for developing objectives that are **specific**, **measurable**, **achievable**, **realistic**, **and time-bound**:

Specific -

Includes the "who" and "what" of program activities. Use only one action verb to avoid issues with measuring success. For example, "Outreach workers will administer the HIV risk assessment tool to at least 100 injection drug users in the population of focus" is a more specific objective than "Outreach workers will use their skills to reach out to drug users on the street."

Measurable -

How much change is expected. It must be possible to count or otherwise quantify an activity or its results. It also means that the source of and mechanism for collecting measurement data can be identified and that collection of the data is feasible for your program. A baseline measurement is required to document change (e.g., to measure the percentage of increase or decrease). If you plan to use a specific measurement instrument, it is recommended that you incorporate its use into the objective. Example: By 9/20 increase by 10 percent the number of 8th, 9th, and 10th grade students who disapprove of marijuana use as measured by the annual school youth survey.

Achievable -

Objectives should be attainable within a given time frame and with available program resources. For example, "The new part-time nutritionist will meet with seven teenage mothers each week to design a complete dietary plan" is a more achievable objective than "Teenage mothers will learn about proper nutrition."

Realistic -

Objectives should be within the scope of the project and propose reasonable programmatic steps that can be implemented within a specific time frame. For example, "Two ex-gang members will make one school presentation each week for two months to raise community awareness about the presence of gangs" is a more realistic objective than "Gang-related violence in the community will be eliminated."

Time-bound -

Provide a time frame indicating when the objective will be measured or a time by when the objective will be met. For example, "Five new peer educators will be recruited by the second quarter of the first funding year" is a better objective than "New peer educators will be hired."

Examples:

Non-SMART Objective	Critique	SMART Objective
Teachers will be trained on the selected evidence-based substance misuse prevention curriculum.	The objective is not SMART because it is not specific, measurable, or time-bound. It can be made SMART by specifically indicating who is responsible for training the teachers, how many will be trained, who they are, and by when the trainings will be conducted.	By June 1, 2020, LEA supervisory staff will have trained 75% of health education teachers in the local school district on the selected, evidence-based substance misuse prevention curriculum.
90% of youth will participate in classes on assertive communication skills.	This objective is not SMART because it is not specific or time-bound. It can be made SMART by indicating who will conduct the activity, by when, and who will participate in the lessons on assertive communication skills.	By the end of the 2020 school year, district health educators will have conducted classes on assertive communication skills for 90% of youth in the middle school receiving the substance misuse and HIV prevention curriculum.
Train individuals in the community on the prevention of prescription drug/opioid overdoserelated deaths.	This objective is not SMART as it is not specific, measurable or time-bound. It can be made SMART by specifically indicating who is responsible for the training, how many people will be trained, who they are, and by when the training will be conducted.	By the end of year two of the project, the Health Department will have trained 75% of EMS staff in the County Government on the selected curriculum addressing the prevention of prescription drug/opioid overdose-related deaths.

Appendix F – Developing the Plan for Data Collection and Performance Measurement

Information in this Appendix should be taken into consideration when developing a response for criteria in Section E of the Project Narrative.

Data Collection:

In describing your plan for data collection, consider addressing the following points:

- What electronic data collection software that will be used?
- How often data will be collected?
- The organizational processes that will be implemented to ensure the accurate and timely collection and input of data.
- The staff that will be responsible for collecting and recording the data.
- The data source/data collection instruments that will be used to collect the data.
- How well the data collection methods will take into consideration the language, norms, and values of the population(s) of focus.
- How will the data be kept secure.
- If applicable, how will the data collection procedures ensure that confidentiality is protected, and that informed consent is obtained. and
- If applicable, how data will be collected from partners, sub-awardees.

It is not necessary to provide information related to data collection and performance measurement in a table, but the following samples may give you some ideas about how to display the information.

Table 1 [provides an example of how information for the required performance measures could be displayed]

Performance Measures	Data Source	Data Collection Frequency	Responsible Staff for Data Collection	Method of Data Analysis

Table 2 [provides an example of how information could be displayed for the data that will be collected to measure the objectives that are included in B.1]

Objective	Data Source	Data Collection Frequency	Responsible Staff for Data Collection	Method of Data Analysis
Objective 1.a				

Objective	Data Source	Data Collection Frequency	Responsible Staff for Data Collection	Method of Data Analysis
Objective 1.b				

Data Management

Points to consider:

- How data will be protected, including information about who will have access to data.
- How will data be stored.
- The staff member who will be responsible for tracking the performance measures and measurable objectives.
- Who will be responsible for conducting the data analysis, including the role of the Evaluator?
- What data analysis methods will be used.
- Who will be responsible for completing the reports?
- How will the data be reported to staff, stakeholders, SAMHSA, Advisory Board, and other relevant project partners.

Data Monitoring

Points to consider:

- How frequently performance data will be reviewed.
- How will you use this data to monitor and evaluate activities and processes and to assess the progress that has been made achieving the goals and objectives?
- Who will be responsible for monitoring the data?

How Data Will Be Used to Enhance the Project/Quality Improvement (QI):

Points to consider:

- If applicable, the QI model that will be used.
- How will the QI process be used to track progress?
- The staff members who will be responsible for overseeing these processes.
- How you will implement any needed changes in project implementation and/or project management.
 - What decision-making processes will be used.
 - When and by whom will decisions be made concerning project improvement.
 - What are the thresholds for determining that changes need to be made?
- Will the Advisory Board have a role in the QI process?
- How will the changes be communicated to staff and/or partners/sub-awardees?

Appendix G – Biographical Sketches and Position Descriptions

Include position descriptions and biographical sketches for all project staff as supporting documentation to the application. The formatting requirements outlined in Appendix B are not applicable for these documents.

Biographical Sketch

Existing curricula vitae of project staff members may be used if they are updated and contain all items of information requested below. You may add any information items listed below to complete existing documents. For development of new curricula vitae include items below in the most suitable format:

- 1. Name of staff member
- 2. Educational background: school(s), location, dates attended, degrees earned (specify year), major field of study
- 3. Professional experience
- 4. Recent relevant publications

Position Description

- 1. Title of position
- 2. Description of duties and responsibilities
- 3. Qualifications for position
- 4. Supervisory relationships
- 5. Skills and knowledge required
- 6. Amount of travel and any other special conditions or requirements
- 7. Salary range
- 8. Hours per day or week

Appendix H – Addressing Behavioral Health Disparities

SAMHSA expects recipients to submit a Behavioral Disparity Impact Statement (DIS) within 60 days of receiving the grant award. The DIS is a data-driven, quality improvement effort to ensure under-resourced populations are addressed in the grant. The DIS is built on the required GPRA data such that no additional data collection is required. It is expected that the DIS will be no more than two pages in length.

The DIS consists of three components:

- (1) Number of individuals to be served during the grant period and identify underresourced population(s) (i.e., racial, ethnic, sexual, and gender minority groups) vulnerable to behavioral health disparities.
- (2) A quality improvement plan to address under-resourced population differences based on the GPRA data on access, use and outcomes of service activities.
- (3) Methods for the development of policies and procedures to ensure adherence to the <u>Behavioral Health Implementation Guide for the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care.</u>

As part of SAMHSA's Disparity Impact Statement requirements, include the number of unduplicated individuals to be served by under-resourced populations in the grant implementation area provided in a table that covers the entire grant period. The under-resourced population(s) should be identified in a narrative that includes a description of the population and a rationale for how the determination was made. Include demographic data and an environmental scan of the population(s) of focus. For data about your population(s) of focus, refer to

https://www.census.gov/about/partners/cic.html. Indicate what the disparity(ies) is and how your services and activities will be monitored and implemented to close the gap(s). In addition, describe how you will evaluate and disseminate the findings to your stakeholders.

Examples of a DIS are available on the SAMHSA website at http://www.samhsa.gov/grants/grants-management/disparity-impact-statement.

Definition of Health Disparities

Healthy People 2030 defines a health disparity as a "particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; disability; mental health; cognitive, sensory, or physical disability;

sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion."

Social Determinants of Health (SDOH)

<u>SDOH</u> are the conditions in the environment where people are born, live, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. SDOH can be grouped into 5 domains:

- Economic Stability
- Education Access and Quality
- Health Care Access and Quality
- Neighborhood and Built Environment
- Social and Community Context

For more information about SDOH Z codes and how SDOH are being used to narrow the health disparities gaps, see https://www.cms.gov/files/document/zcodes-infographic.pdf; https://www.cms.gov/files/document/cms-omh-january2020-zcode-data-highlightpdf.pdf; and https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6207437/pdf/18-095.pdf

Definition of Health Equity

Health equity involves ensuring that everyone has a fair and just opportunity to be as healthy as possible. Behavioral health equity is the right to access quality health care for all populations regardless of the individual's race, ethnicity, gender, socioeconomic status, sexual orientation, or geographical location. This includes access to prevention, harm reduction, treatment, and recovery services for mental and substance use disorders.

Under-resourced populations

SAMHSA grant applicants are routinely asked to define the population they intend to serve given the focus of a particular grant program (e.g., adults with opioid use disorders at risk of overdose; adults with serious mental illness [SMI]; adolescents engaged in underage drinking; populations at risk for contracting HIV/AIDS, etc.). Within these populations of focus are *under-resourced populations* that may have unequal access to, use of, or outcomes from provided services. These disparities may be the result of differences in race, ethnicity, language, culture, and/or socioeconomic factors specific to that under-resourced population. For instance, Latino adults with opioid use disorder may be at heightened risk for overdoses due to lack of in-language prevention campaigns and treatment; African Americans with an SMI may more likely terminate treatment prematurely due to lack of providers with whom they can develop a therapeutic relationship; Native American youth may have an increased incidence of underage drinking due to coping patterns related to historical trauma; and African

American women may be at greater risk for contracting HIV/AIDS due to lack of access to education on risky sexual behaviors in urban low-income communities, etc. While these factors might not be pervasive among the general population served by a recipient, they may be predominant among under-resourced populations or groups vulnerable to disparities. It is imperative that recipients understand who is being served, who is under-resourced, and who is not being served within their community in order to provide outreach and care that will yield positive outcomes, per the focus of the grant. For organizations to attend to the potentially disparate impact of their grant efforts, recipients are asked to address access, use and outcomes, disaggregated by under-resourced populations. Under-resourced populations can be defined by the following factors:

- By race
- By ethnicity
- By gender (including transgender populations)
- By sexual orientation (including lesbian, gay and bisexual populations)

Access refers to which populations/under-resourced populations are being served/reached by the grant program. Use refers to what interventions/services are received by the various populations. Outcomes refers to the outcome measures stipulated by the grant and examined across under-resourced populations.

Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS Standards)

The ability to address the quality of care provided to under-resourced populations served within SAMHSA's grant programs is enhanced by programmatic alignment with the federal National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS Standards).

The CLAS Standards are comprised of 15 Standards that provide a blueprint for health and health care organizations to implement culturally and linguistically appropriate, respectful, and responsive services that will advance health equity, improve quality, and help eliminate health care disparities.

The CLAS Standards are grouped into a Principal Standard and three themes focused on

- 1) Governance and Leadership.
- 2) Communication and Language Assistance.
- 3) Engagement, Continuous Improvement and Accountability.

Widely embraced by States and health care systems, the National CLAS Standards are more recently being promoted in behavioral health care, which includes a Behavioral Health CLAS Implementation Guide at

https://www.minorityhealth.hhs.gov/Assets/PDF/clas%20standards%20doc_v06.28.21.pdf. You can learn more about the CLAS mandates, guidelines, and recommendations at: http://www.ThinkCulturalHealth.hhs.gov.

Guidelines for behavioral health implementation of the CLAS Standards can be found at https://thinkculturalhealth.hhs.gov/clas. This document addresses the importance of improving access to behavioral health care, promoting quality behavioral health programs and practice, and ultimately reducing persistent disparities in mental health and substance use prevention, harm reduction, treatment, and recovery for underresourced, minority populations and communities.

Appendix I – Standard Funding Restrictions

HHS codified the *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards*, 45 CFR Part 75. In Subpart E, cost principles are described and allowable and unallowable expenditures for HHS recipients are delineated. 45 CFR Part 75 is available at https://ecfr.federalregister.gov/current/title-45/subtitle-A/subchapter-A/part-75. Unless superseded by program statute or regulation, follow the cost principles in 45 CFR Part 75 and the standard funding restrictions below.

You may also reference the SAMHSA site for grantee guidelines on financial management requirements at https://www.samhsa.gov/grants/grants-management/policies-regulations/financial-management-reguirements.

SAMHSA grant funds may not be used to:

- SAMHSA grant funds may not be used to purchase, prescribe, or provide marijuana or treatment using marijuana. See, e.g., 45 C.F.R. 75.300(a) (requiring HHS to ensure that Federal funding is expended in full accordance with U.S. statutory and public policy requirements); 21 U.S.C. 812(c)(10) and 841 (prohibiting the possession, manufacture, sale, purchase, or distribution of marijuana).
- Pay for promotional items including, but not limited to, clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags. (See 45 CFR 75.421(e)(3))
- Pay for the purchase or construction of any building or structure to house any part of the program. Minor alterations and renovations (A&R) may be authorized for up to 25 percent of a given budget period or \$150,000 (whichever is less) for existing facilities, if necessary and appropriate to the project. Minor A&R may not include a structural change (e.g., to the foundation, roof, floor, or exterior or loadbearing walls of a facility, or extension of an existing facility) to achieve the following: Increase the floor area; and/or, change the function and purpose of the facility. All minor A&R must be approved by SAMHSA.
- Provide inpatient treatment or hospital-based detoxification services. Residential services are not considered to be inpatient or hospital-based services.
- Make direct payments to individuals to enter treatment or continue to participate in prevention or treatment services (See 42 U.S.C. § 1320a-7b).

Note: A recipient or treatment or prevention provider may provide up to \$30 non-cash incentive to individuals to participate in required data collection follow-up.

This amount may be paid for participation in each required follow-up interview. For programs including contingency management as a component of the treatment program, each individual contingency must be \$15 or less in value and clients may not receive contingencies totaling more than \$75 per budget period.

- Meals are generally unallowable unless they are an integral part of a conference grant or specifically stated as an allowable expense in the NOFO (See https://www.hhs.gov/grants/contracts/contract-policies-regulations/spending-on-food/index.html)
- General Provisions under Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act Public Law 116-260, Consolidated Appropriations Act, 2021, Division H, Title V, Section 527, notwithstanding any other provision of this Act, no funds appropriated in this Act shall be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug. Provided, that such limitation does not apply to the use of funds for elements of a program other than making such purchases if the relevant State or local health department, in consultation with the Centers for Disease Control and Prevention, determines that the State or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and such program is operating in accordance with state and local law.
- Salary Limitation: The Consolidated Appropriations Act, 2021 (Public Law 116-260), Division H, Title II, Section 202, provides a salary rate limitation. The law limits the salary amount that may be awarded and charged to SAMHSA grants and cooperative agreements. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II, which is \$203,700. This amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of the duties to your organization. This salary limitation also applies to subrecipients under a SAMHSA grant or cooperative agreement. Note that these or other salary limitations will apply in the following fiscal years, as required by law.

Appendix J – Intergovernmental Review (E.O. 12372) Requirements

States with SPOCs

All SAMHSA grant programs are covered under Executive Order (EO) 12372, as implemented through Department of Health and Human Services (DHHS) regulation at 45 CFR Part 100. Under this Order, states may design their own processes for reviewing and commenting on proposed federal assistance under covered programs. Certain jurisdictions have elected to participate in the EO process and have established State Single Points of Contact (SPOCs). Information on the SPOC for participating states can be found at: https://www.whitehouse.gov/wp-content/uploads/2020/04/SPOC-4-13-20.pdf

You do not need to do this if you are an American Indian/Alaska Native tribe or tribal organization. If your state participates, contact your SPOC as early as possible to alert him/her to the prospective application(s) and to receive any necessary instructions on the state's review process. For proposed projects serving more than one state, you are advised to contact the SPOC of each affiliated state.

The SPOC should send any state review process recommendations to the following address within 60 days of the application deadline:

Director, Division of Grants Management Office of Financial Resources, ATTN: SPOC – Funding Announcement No. TI-22-013 Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Room 17E20 Rockville, MD 20857

States without SPOCs

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If your state does not have a SPOC and you are a community-based, non-governmental service provider, you must submit a Public Health System Impact Statement (PHSIS)⁵ to the head(s) of appropriate state and local health agencies in the area(s) to be affected no later than the application deadline. The PHSIS is intended to keep state and local health officials informed of proposed health services grant applications submitted

⁵ Approved by OMB under control no. 0920-0428; Public reporting burden for the Public Health System Reporting Requirement is estimated to average 10 minutes per response, including the time for copying the first page of SF-424 and the abstract and preparing the letter for mailing. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0920-0428. Send comments regarding this burden to CDC Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0428).

by community-based, non-governmental organizations within their jurisdictions. If you are a <u>state or local government or American Indian/Alaska Native tribe or tribal</u> organization, you are not subject to these requirements.

The PHSIS consists of the following information:

- A copy of the first page of the application (SF-424); and
- A summary of the project, no longer than one page in length that provides: 1)
 a description of the population to be served; 2) a summary of the services to
 be provided; and 3) a description of the coordination planned with appropriate
 state or local health agencies.

For SAMHSA grants, the appropriate state agencies are the Single State Agencies (SSAs) for substance misuse and mental health. A listing of the SSAs for substance misuse and the SSAs for mental health can be found on SAMHSA's website at http://www.samhsa.gov/grants/applying/forms-resources. If the proposed project falls within the jurisdiction of more than one state, you should notify all representative SSAs.

Review Section IV of the NOFO carefully to determine if you must include an attachment with a copy of a letter transmitting the PHSIS to the SSA. The letter must notify the state that, if it wishes to comment on the proposal, its comments should be sent no later than 60 days after the application deadline to the following address:

Director of Grants Management
Office of Financial Resources,
ATTN: SSA – Funding Announcement No. TI-22-013
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane, Room 17E20
Rockville, MD 20857

In addition, applicants may request that the SSA send them a copy of any state comments. The applicant must notify the SSA within 30 days of receipt of an award.

Appendix K – Administrative and National Policy Requirements

If your application is funded, you must comply with all terms and conditions of the NoA. SAMHSA's standard terms and conditions are available on the SAMHSA website.

HHS Grants Policy Statement (GPS)

If your application is funded, you are subject to the requirements of the HHS Grants Policy Statement (GPS) that are applicable based on recipient type and purpose of award. This includes any requirements in Parts I and II of the HHS GPS that apply to the award. The HHS GPS is available at http://www.samhsa.gov/grants/grants-management/policies-regulations/hhs-grants-policy-statement. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary (as specified in the NoA).

HHS Grant Regulations

If your application is funded, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions. For more information see the SAMHSA website at http://www.samhsa.gov/grants/grants-management/policies-regulations/requirements-principles.

Additional Terms and Conditions

Depending on the nature of the specific funding opportunity and/or your proposed project as identified during review, SAMHSA may negotiate additional terms and conditions with you prior to grant award. These may include, for example:

- actions required to be in compliance with confidentiality and participant protection/human subjects requirements;
- o requirements relating to additional data collection and reporting;
- o requirements relating to participation in a cross-site evaluation;
- requirements to address problems identified in review of the application; or revised budget and narrative justification.

Performance Goals and Objectives

If your application is funded, you will be held accountable for the information provided in the application relating to performance targets. SAMHSA program officials will consider your progress in meeting goals and objectives, as well as your failures and strategies for overcoming them, when making an annual recommendation to continue the grant and the amount of any continuation award. Failure to meet stated goals and objectives

may result in suspension or termination (see <u>2 CFR 200.202</u>, <u>2 CFR 200.301</u> and <u>2 CFR 200.329</u>) of the grant award, or in reduction or withholding of continuation awards.

Termination of Federal Award

Note that the OMB revisions to Guidance for Grants and Agreements termination provisions located at <u>2 CFR § 200.340</u> - Termination apply to all federal awards effective August 13, 2020.

Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

- Recipients of FFA must ensure that their programs are accessible to persons
 with limited English proficiency. For guidance on meeting your legal obligation to
 take reasonable steps to ensure meaningful access to your programs or activities
 by limited English proficient individuals. See https://www.lep.gov/.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications, and making services accessible to them, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your program in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

Acknowledgement of Federal Funding

As required by HHS appropriations acts, all HHS recipients must acknowledge Federal funding when issuing statements, press releases, publications, requests for proposal, bid solicitations, and other documents, such as tool-kits, resource guides, websites, and presentations describing the projects or programs funded in whole or in part with HHS federal funds. The recipient must clearly state: 1) the percentage and dollar amount of the total costs of the program or project funded with federal money; and 2) the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

Supplement Not Supplant

Grant funds may be used to supplement existing activities. Grant funds may not be used to supplant current funding of existing activities. "Supplant" is defined as replacing funding of a recipient's existing program with funds from a federal grant (2 CFR Part 200, Appendix XI).

Mandatory Disclosures

A term may be added to the NoA which states: Consistent with 45 CFR 75.113, applicants and recipients must disclose in a timely manner, in writing to the HHS awarding agency, with a copy to the HHS Office of Inspector General (OIG), all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Sub-recipients must disclose, in a timely manner, in writing to the prime recipient (pass through entity) and the HHS OIG, all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to SAMHSA at the following address:

SAMHSA

Attention: Office of Financial Advisory Services

5600 Fishers Lane Rockville, MD 20857

AND by email to grantdisclosures@oig.hhs.gov or by mail to the following address:

Office of Counsel to the Inspector General Office of the Inspector General U.S. Dept. of Health and Human Services Grant Self-Disclosures 330 Independence Avenue SW Cohen Building Room 5527 Washington, DC 20201

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance; including suspension or debarment (See 2 CFR parts 180 & 376 and 31 U.S.C. 3321)."

System for Award Management (SAM) Reporting

A term may be added to the NoA that states: "In accordance with the regulatory requirements provided at 45 CFR 75.113, 2 CFR 25, and Appendix XII to 45 CFR Part 75, recipients that have currently active federal grants and procurement contracts with cumulative total value greater than \$10,000,000, must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a federal award that reached final disposition within the most recent five-year period. The recipient also must make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75."

Drug-Free Workplace

A term may be added to the NoA that states: "You as the recipient must comply with drug-free workplace requirements in Subpart B (or Subpart C, if the recipient is an individual) of part 382, which adopts the Government-wide implementation (2 CFR part 182) of section 5152-5158 of the Drug-Free Workplace Act of 1988 (Pub. L. 100-690, Title V, Subtitle D; 41 U.S.C. 701-707)."

Smoke-Free Workplace

The Public Health Service strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. Further, 20 USC 6081 et seq., the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

Standards for Financial Management

Recipients are required to meet the standards and requirements for financial management systems set forth in 45 CFR part 75 Subpart D. The financial systems must enable the recipient to maintain records that adequately identify the sources of funds for federally assisted activities and the purposes for which the award was used, including authorizations, obligations, unobligated balances, assets, liabilities, outlays or expenditures, and any program income. The system must also enable the recipient to compare actual expenditures or outlays with the approved budget for the award.

SAMHSA funds must retain their award-specific identity – they may not be commingled with state funds or other federal funds. ["Commingling funds" typically means depositing or recording funds in a general account without the ability to identify each specific source of funds for any expenditure.]. Common mistakes related to comingling are outlined below:

- Commingling of Cost Centers. Every business activity constitutes a cost center.
 Examples of cost centers include: a federal grant, a state grant, a private grant, matching costs for a specific grant, a self-funded project, fundraising activities, membership activities, lines of business, unallowable costs, indirect costs, etc.
 Recipients must establish a unique account(s) in the accounting system to capture and accumulate expenditures of each cost center, apart from other cost centers.
- Commingling of Cost Categories. Recipients must avoid budget fluctuations that
 violate programmatic restrictions. They must also avoid applying indirect cost
 rates to prohibited cost categories, such as equipment, participant support costs
 and subcontracts/subawards in excess of \$25,000. As a result, recipients must
 establish unique object codes in the accounting system to capture and
 accumulate costs by budget category (i.e., salaries, fringe benefits, consultants,
 travel, participant support costs, subcontracts, etc.).
- Commingling of Time Worked and Not Worked. Recipients may not directly
 charge a grant for employees' time not spent working on the grant. Therefore,
 Paid Time Off (PTO), such as vacation, holiday, sick and other paid leave, is not
 recoverable directly from grants, but rather must be allocated to all grants,
 projects, and cost centers over an entire cost accounting period through either an
 indirect cost or fringe benefit rate.
- Unsupported Labor Costs. To support charges for direct and indirect salaries and wages, recipients maintaining hourly timesheets must ensure that timesheets encompass all hours worked and not worked on a daily basis. The timesheet should identify the: (a) grant, project or cost center being worked on; (b) number of hours worked on each; (c) description of work performed; and (d) Paid Time Off (PTO) hours. The total hours recorded each day should coincide with an individual's employment status in accordance with established policy (i.e., full-time employees work 8 hours each day, etc.).
- Inconsistent Treatment of Costs. Recipients must treat costs consistently across all federal and non-federal grants, projects, and cost centers. For example, recipients may not direct-charge federal grants for costs typically considered indirect in nature, unless done consistently. Examples of indirect costs include administrative salaries, rent, accounting fees, utilities, etc. Additionally, in most cases, the cost to develop an accounting system adequate to justify direct charging of the aforementioned items outweighs the benefits. As a result, use of an indirect cost rate is the most effective mechanism to recover these costs and not violate federal financial requirements of consistency, allocability and

allowability. See the appendix titled "Sample Budget and Justification," for additional indirect cost guidance.

Trafficking in Persons

Awards issued by SAMHSA are subject to the requirements of <u>2 CFR part 175</u> and <u>22 USC 7104(g)</u>. For the full text of the award term, go to http://www.samhsa.gov/grants/grants-management/notice-award-noa/standard-terms-conditions.

NOTE: The signature of the AOR on the application serves as the required certification of compliance for your organization regarding the administrative and national policy requirements.

Publications

Recipients are required to notify the Government Project Officer (GPO) of any materials based on the SAMHSA-funded grant project that are accepted for publication. In addition, SAMHSA requests that recipients:

- Provide the GPO with advance copies of publications.
- Include acknowledgment of the SAMHSA grant program as the source of funding for the project.
- Include a disclaimer stating that the views and opinions contained in the publication do not necessarily reflect those of SAMHSA or the U.S.
 Department of Health and Human Services and should not be construed as such.

SAMHSA reserves the right to issue a press release about any publication deemed by SAMHSA to contain information of program or policy significance to the substance misuse treatment/substance misuse prevention/mental health services community.

Appendix L – Sample Budget and Justification

All applications must have a detailed budget justification and narrative that explains the federal and the non-federal expenditures broken out by the object class cost categories listed on SF-424A – Section B (Budget Category) for non-construction awards.

- The budget narrative must match the costs identified on the SF-424A form and the total costs on the SF-424.
- The Budget Narrative and justification must be consistent with and support the Project Narrative.
- The Budget Narrative and justification must be concrete and specific. It must provide a justification for the basis of each proposed cost in the budget and how that cost was calculated. Examples to consider when justifying the basis of your estimates can be ongoing activities, market rates, quotations received from vendors, or historical records. The proposed costs must be reasonable, allowable, allocable, and necessary for the supported activity.
- NOFOs invite applications for periods of performance of one to up to five years. Generally, awards, on a competitive basis, will be for a one-year budget period but the period of performance may be up to five years. Submission and SAMHSA approval of the progress report(s) and any other required submission or reports is the basis for the budget period renewal and release of subsequent year funds. Funding beyond the one-year budget period but within the multi-year period of performance is subject to availability of funds, satisfactory progress of the recipient, and a determination that continued funding would be in the best interest of the Federal Government. Progress will be evaluated by submission of data on required performance measures, satisfactory achievement of identified goals and objectives, providing services to the projected number of individuals specified in the application, and satisfactory resolution of barriers and challenges that arise in the implementation of the project.
- Refer to the program specific Funding Restrictions/Limitations and the Standard Funding Restrictions in the NOFO, as well as to 45 CFR Part 75 (https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75, for applicable administrative requirements and cost principles.

SAMHSA Budget Template

To expedite review of your application, it is highly recommended you use the following PDF budget template to complete the Detailed Budget and Narrative Justification for submission with your application:

- To locate the budget template <u>Click here SAMHSA Forms and Resources</u> scroll down to "SAMHSA Budget Template" section. You must download the budget template PDF to your computer first before opening it directly in Adobe Acrobat or Acrobat Reader (not your internet browser):
 - Right-click the link "SAMHSA Budget Template (PDF)"
 - 2. Select "save link as" and save to a location on your computer
 - 3. Go to the saved location and open the "SAMHSA Budget Template (PDF)" using Adobe Acrobat or Acrobat Reader.

Guidance

The following documents provide guidance on using the budget template:

- Key Features of the Budget Template
- Budget Template Users Guide
- <u>Budget Review Checklist</u> use this checklist to review your Detailed Budget and Narrative Justification before submission to SAMHSA.

Note: For SAMHSA to view all of your budget data, you must convert the PDF to a non-editable format by **PRINTING TO PDF** before submission.

Sample Budgets

The following PDFs are samples of Detailed Budgets and Narrative Justification:

• Sample Budget – NON-MATCH (PDF | 697 KB)

Completing the SF-424A

Complete Sections A – F of the SF-424A Budget Information – Non-Construction Programs form included with the application package for each year of the period of performance. The budget period is for one year. However, you must submit one-year budgets for each of the subsequent budget periods within the requested period of performance at the time of application.

In **Section A** use rows 1–4 to provide the budget amounts for the first four years of the project. Enter the amounts in the "New or Revised Budget" column- not the "Estimated Unobligated Funds" column. In Section B 6. Object Class Categories of the SF-424A, provide the object class category breakdown (i.e., line-item budget) for each year of the period of performance specified in Section A.

In **Section B**, use column (1) to provide category amounts for year one and use columns (2) through (4), if applicable, for subsequent budget years. If applicable for

year five, submit a copy of Section B of the SF-424A as an Attachment (specific attachment number will be listed in the NOFO - not counted in the page limit).

Section C – Non-Federal Resources: complete only if Section III. 2. Cost Sharing/Matching of the NOFO indicates that cost sharing/matching is required. Lines 8–11 correspond to the first four years of the project. If applicable for year five, submit a copy of Section C of the SF-424A as an Attachment (specific attachment number will be listed in the NOFO).

Section D – Forecasted Cash Needs: If no cost sharing/matching is required, complete only line "13. Federal" in the first column titled "Total for 1st Year." If cost sharing/matching is required, complete all three lines "13. Federal," "14. Non-Federal," and "15. Total (Sum of lines 13 and 14)" in the first column titled "Total for 1st Year."

Section E – Budget Estimates of Federal Funds Needed for Balance of the **Project:** Complete line 16 of the Future Funding Periods columns for the out years, with (b) First being the 2nd year, (c) Second being the 3rd year, etc.

Section F – Other Budget Information. Complete as appropriate.

Budget Cost Categories

<u>Personnel Costs</u>: Explain personnel costs by listing each staff member who will be supported from funds, name (if possible), position title, percentage of full-time equivalency, and annual salary. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II or **\$203,700**. An individual's base salary, per se, is NOT constrained by the statutory provision for a limitation of salary. The rate limitation simply limits the amount that may be awarded and charged to SAMHSA grants and cooperative agreements.

Note: If an organization is awarded a grant and chooses to move forward with hiring an individual for a Key Personnel position before receiving SAMHSA's formal approval, this will be done at the organization's own risk. If SAMHSA's review of the Key Personnel request results in the proposed individual not being approved or deemed not qualified for the position, the expectation is that the organization must submit a qualified candidate to be placed in the Key Personnel position. SAMHSA will not be liable for any costs incurred or pay for salaries of a Key Personnel that is not approved or deemed not qualified on the grant program.

<u>Fringe Benefits</u>: List the components that comprise the fringe benefit rate, for example health insurance, taxes, unemployment insurance, life insurance, retirement plans, and tuition reimbursement. The fringe benefits should be directly proportional to that portion of personnel costs that are allocated for the project.

<u>Travel</u>: List travel costs according to local and long-distance travel. For local travel, outline the mileage rate, number of miles, reason for travel and staff member/consumers completing the travel. The budget should also reflect the travel expenses (e.g., airfare, lodging, parking, per diem, etc.) for each person and trip associated with participating in meetings and other proposed trainings or workshops. Name the traveler(s) if possible, describe the purpose of the travel, provide number of trips involved, the destinations, and the number of individuals for whom funds are requested.

<u>Equipment</u>: List equipment costs and provide justification for the need of the equipment to carry out the program's goals. Extensive justification and a detailed status of current equipment must be provided when requesting funds for the purchase of items that meet the definition of equipment (a unit cost of \$5,000 or more and a useful life of one or more years). For example, large items of medical equipment.

<u>Supplies</u>: List the items that the project will use to implement the proposed project. Items must be listed separately: office supplies (e.g., paper, pencils).

Per 45 CFR § 75.321, property will be classified as supplies if the acquisition cost is under \$5,000. Note that items such as laptops, tablets, and desktop computers are classified as a supply if the value is under the \$5,000 equipment threshold.

Contractual/Subawards/Consortium/Consultant: Provide a clear explanation as to the purpose of each contract/subaward, how the costs were estimated, and the specific contract/subaward deliverables. You should provide the basis for your cost estimate for the contract. You are responsible for ensuring that your organization or institution has in place an established and adequate procurement system with fully developed written procedures for awarding and monitoring all contracts/subawards. Recipients must notify potential subrecipients that entities receiving subawards must be registered in SAM and provide the recipient with their DUNS number (see 2 CFR part 25). For consultant services, list the total costs for all consultant services. In the budget narrative, identify each consultant, the services he/she will perform, total number of days, travel costs, and total estimated costs.

For subawards to entities that will help carry out the work of the award, you should describe how you will monitor their work to ensure the funds are being properly used.

Other: Include all costs that do not fit into any other category and provide an explanation of each cost in this category (e.g., provider licenses). In some cases, rent, utilities, and insurance fall under this category if they are not included in an approved indirect cost rate.

<u>Indirect Costs</u>: Indirect costs are those costs incurred for common or joint objectives which cannot be readily and specifically identified with a particular project or program but are necessary to the operations of the organization, e.g., the cost of operating and

maintaining facilities, depreciation, and administrative salaries. For some institutions, the term "facilities and administration" (F&A) is used to denote indirect costs. If your organization does not have an indirect cost rate, you may wish to obtain one through HHS's Cost Allocation Services (CAS) (formerly the Division of Cost Allocation (DCA)). Visit CAS's website to learn more about rate agreements, the process for applying for them, and the regional offices which negotiate them. If indirect costs are included in the budget, attach a copy of the indirect cost rate agreement.

Any non-federal entity that has never received a negotiated indirect cost rate, (except a governmental department or agency unit that receives more than \$35 million in direct federal funding) may elect to charge a de minimis rate of 10 percent of modified total direct costs (MTDC) which may be used indefinitely. If chosen, this methodology once elected must be used consistently for all federal awards until such time as a non-federal entity chooses to negotiate for a rate, which the nonfederal entity may apply to do at any time.